

ESTTA Tracking number: **ESTTA661962**

Filing date: **03/19/2015**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91194218
Party	Defendant Meridian Bioscience, Inc.
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Date	03/19/2015
Attachments	Possemato Full.pdf(226145 bytes) Possemato Cert.pdf(48281 bytes) Possemato Exhibit B.pdf(800311 bytes) Possemato Exhibit 54.pdf(206390 bytes) Possemato Exhibit 202.pdf(5306951 bytes) Possemato Exhibit 206.pdf(154154 bytes) Possemato Exhibit 214.pdf(414434 bytes) Possemato Exhibit 215.pdf(1267807 bytes) Possemato Exhibit 230.pdf(362624 bytes)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

ILLUMINA, INC.,)
)
OPPOSER,)
)
vs.) OPPOSITION NO:
) 91211615
MERIDIAN BIOSCIENCE, INC.,)
)
APPLICANT.)
_____)

DEPOSITION OF KAREN POSSEMATO
December 4, 2014 - 2:23 p.m.

Deposition of KAREN POSSEMATO, taken on behalf of the Applicant, Meridian Bioscience, Inc., at 12790 El Camino Real, San Diego, California, commencing at 2:23 p.m., on Thursday, December 4, 2014, before Tracy M. Fox, CSR Number 10449, Certified Shorthand Reporter in and for the State of California

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1

I N D E X

2

WITNESS:

EXAMINED BY:

PAGE:

3

KAREN POSSEMATO

MR. HANKINSON

6

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6

E X H I B I T S

7

8

EXHIBIT NUMBER:

DESCRIPTION:

PAGE:

9

Possemato Exhibit B

Declaration of Karen

10

Possemato (15 pages)

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Possemato Exhibit 54

Articles regarding

13

Luminex, Bates-stamped

14

ILLUM-0708 through

15

ILLUM-0711 (5 pages)

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Possemato Exhibit 202

Various articles regarding

17

Illumina, Bates-stamped

18

ILLUM-0810 through

19

ILLUM-0855, and ILLUM-0959

20

through ILLIM-0980

21

(84 pages)

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1	I N D E X (Continued)		
2	Possemato Exhibit 206 Article entitled		
3	"Verinata Health's Verifi		
4	Prenatal Test Available		
	through the California		
5	Prenatal Screening Program,"		
6	Bates-stamped ILLUM-1807		
7	through ILLUM-1808		
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10	Possemato Exhibit 214 Various documents,		
11	Bates-stamped ILLUM-0857		
12	through ILLUM-0863		
13	(8 pages)	99	
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15	Possemato Exhibit 215 Various Illuminotes		
16	documents, Bates-stamped		
17	ILLUM-0864 through		
18	ILLUM-0880 (21 pages)	104	
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20	Possemato Exhibit 230 Articles from a GenomeWeb		
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1 SAN DIEGO, CALIFORNIA, THURSDAY

2 DECEMBER 4, 2014

3 2:23 P.M.

4

5 KAREN POSSEMATO,

6 called as a witness and sworn in by

7 the deposition officer, was examined

8 and testified as follows:

9

10 DEPOSITION OFFICER: Would you raise your

11 right hand.

12 Do you solemnly state that the testimony

13 you are about to give in the following deposition

14 will be the truth, the whole truth, and nothing but

15 the truth?

16 THE WITNESS: Yes, I do.

17 DEPOSITION OFFICER: Thank you.

18

19 EXAMINATION

20 BY MR. HANKINSON:

21 Q. Good afternoon.

22 Is it Ms. Possemato?

1 A. Very good.

2 Q. Well, I heard it earlier today.

3 Would you please say your name and spell
4 your last name for the record.

5 A. Yes. Karen Possemato, K-a-r-e-n,
6 P-o-s-s-e-m-a-t-o.

7 Q. My name is Tom Hankinson. I represent
8 Meridian in the matter that we're here about today.
9 With me is Mike Hurst, who also represents Meridian.

10 Have you ever been deposed before?

11 A. Yes.

12 Q. How many times?

13 A. Once.

14 Q. And about how long ago was it?

15 A. About two years.

16 Q. All right. What was the nature of that
17 matter? What was it about?

18 A. It was trademarking.

19 Q. Was that in an ongoing litigation or, like
20 here, before the PTO?

21 A. I don't remember, yeah.

22 Q. I'll go through some of the guidelines

1 that you're probably already familiar with, just to
2 make sure that we're on the same page.

3 I'll ask the questions, you'll provide a
4 response.

5 Try to wait until I'm finished asking the
6 question -- even though sometimes I'm very halting
7 and it can be very difficult -- before you give a
8 small pause and then answer so that it's easier to
9 take down both the question and the answer
10 completely.

11 Is that okay?

12 A. Yes, that's fine.

13 Q. And please answer with a word like "Yes"
14 or "No" as opposed to head nods or "Uh-huh" or
15 "Uh-uh" because it can be ambiguous on the record
16 when we do things like that.

17 Is that fair?

18 A. Yes.

19 Q. If you don't understand any of my
20 questions or would like to have them repeated,
21 please tell me. Okay?

22 A. Okay.

1 Q. If you do answer a question, I'm going to
2 assume that you understood it.

3 Is that fair?

4 A. Yes.

5 Q. If you need a break, please go ahead and
6 tell us at any time. You'll have to answer the
7 question that is then pending, if there is one, and
8 then we can take a break.

9 Is that okay?

10 A. Yes.

11 Q. To start, I would just like to get some
12 background information about you.

13 Would you please share with me your
14 education after high school.

15 A. Yes. I have a bachelor's in
16 biochemistry.

17 Q. Where from?

18 A. UC San Diego.

19 Q. Do you have any additional post
20 high-school education?

21 A. No.

22 Q. Do you have any formal training that's

1 applicable in your work, like certifications or
2 courses that you've taken?

3 A. No.

4 Q. And let's run through your work history
5 after you graduated college.

6 What was -- do you think it would be
7 easier to go from then forward, or to start at
8 Illumina and work backward?

9 A. From then forward is fine.

10 Q. Okay. So when did you graduate?

11 A. 1989.

12 Q. And what was your first job?

13 A. Well, it wasn't my first job. But my
14 first job after that was as a research associate at
15 Scripps Clinic and Research Institute.

16 Q. And for how long did that last?

17 A. For about three years.

18 Q. And what was the next position that you
19 took after that?

20 A. So then I moved to a technical support
21 scientist role at what was then Invitrogen.

22 Q. "Invitrogen." Okay. I've been

1 pronouncing that in my head as Invitrogen.

2 Invitrogen. All right. Like "in vitro."

3 I should have known that.

4 You can say "Yes" --

5 A. That's --

6 Q. -- "you should have known that."

7 A. That's -- yeah, that's right.

8 Q. So the technical support scientist role,
9 what did that involve?

10 A. So that involves answering technical
11 questions about products on the phone with
12 customers.

13 Q. How long did you stay at Invitrogen?

14 A. About three-and-a-half years.

15 Q. In the same role, or did you change roles
16 during that time?

17 A. I also did technical writing for a period
18 of time.

19 Q. So you would have started at Invitrogen in
20 roughly 1992, and left in roughly 1996?

21 A. That's correct.

22 Q. When you were a technical support

1 scientist at Invitrogen, what products were you
2 answering questions about?

3 A. There were a variety. But a few of them
4 were FastTrack mRNA isolation, Baculovirus gene
5 expression, Pichia pastoris gene expression,
6 TA Cloning.

7 Q. Now, those all seemed like verbs or
8 gerunds for like a process, like expression in
9 cloning.

10 Were there products or services or both
11 that you were working with?

12 A. Those are all of our product areas.

13 Q. And did Invitrogen provide services or
14 just products?

15 A. At the time they provided both services
16 and products.

17 Q. And were you answering questions about
18 their full line of products and services?

19 A. Yes.

20 Q. Were Invitrogen's products and services
21 used in the field of clinical diagnostics at that
22 time?

1 A. Let's see. So I believe they were used in
2 clinical labs at that time.

3 Q. Were they labeled "Research use only"?

4 A. Yes, they were labeled "Research use
5 only."

6 Q. What was your next job after Invitrogen?

7 A. It was at Qiagen as a product manager.
8 Q-i-a-g-e-n.

9 Q. Q-i-a-g-e-n?

10 A. Yes.

11 Q. It's missing a "U"?

12 A. We always used to say, "There is no 'U' in
13 Qiagen."

14 (LAUGHTER).

15 BY MR. HANKINSON:

16 Q. And the title was --

17 A. Sorry.

18 Q. That's great.

19 And the title was product --

20 A. Product manager.

21 Q. -- manager.

22 And in what year did Qiagen not have you?

1 A. 2004.

2 MR. HORNE: That's your improv skills
3 coming at you.

4 (LAUGHTER.)

5 BY MR. HANKINSON:

6 Q. Were you a product manager during your
7 entire time at Qiagen?

8 A. No.

9 Q. What were your changes in role?

10 A. So I was also a senior product manager and
11 then a market manager and then a senior market
12 manager.

13 Q. Were these positions that interfaced with
14 customers or were internal sort of planning and
15 managing positions?

16 A. They were both internal and external, but
17 primarily external.

18 Q. What sorts of products and/or services did
19 Qiagen sell?

20 A. So at the time, nucleic-acid purification
21 products were a big part of the portfolio, including
22 automation solutions. So hardware for those, as

1 well as transfection, various enzymes.

2 I think that -- I think that pretty well
3 covers it.

4 Q. Equipment and -- well, who -- who were the
5 customers of Qiagen for these products?

6 A. So customers included academic labs in
7 university settings, hospitals, clinical reference
8 labs, hospital labs, government, agricultural.

9 What did I leave out?

10 Pharmaceutical, biotech companies.

11 Pretty much the gamut of folks who used --
12 who use molecular biology reagents.

13 Q. Sorry.

14 We had a discussion about the word "gamut"
15 this morning.

16 Were all of Qiagen's products labeled "For
17 research use only"?

18 A. Yes.

19 Q. Were any of Invitrogen's or Qiagen's
20 products used in lab-developed tests -- or LDTs?

21 A. Yes.

22 Q. Which ones -- which company and which

1 ones? And we can take them one at a time, if you
2 would like.

3 A. Yeah.

4 So -- so Qiagen, by the nature of what it
5 provided, these nucleic-acid solutions, was up front
6 of many, many diagnostic and LDT applications.

7 So whether you needed to -- to purify DNA
8 from a stool sample or from blood or from a biopsy,
9 that was sort of their core strength.

10 So that's why, you know, reference labs
11 and -- and various folks in clinical settings were
12 using the products.

13 Q. And that applied to -- that answer applies
14 to the full line of Qiagen's products --

15 A. Yes.

16 Q. -- is that right?

17 A. For the most part, yes.

18 Q. And what about Invitrogen?

19 A. Invitrogen, at the time their portfolio
20 was -- was much more focused on applications that
21 would be used in a research setting.

22 So although -- you know, for their --

1 again, nucleic-acid purification, the mRNA
2 extraction kit that I mentioned --

3 Q. Uh-huh.

4 A. -- those types of technologies are also
5 fair game up front of clinical applications.

6 But the -- you know, the vast majority of
7 the rest of the portfolio was more targeted at what
8 you would find in what you would consider a research
9 application or a clinical-research application.

10 Q. And that was the FastTrack mRNA
11 extractions?

12 Is that what you said?

13 A. That's correct, yeah.

14 Q. In 2004, what was your next job?

15 A. I joined Illumina as -- at the time I was
16 associate director of marketing.

17 Q. And could you please take me through your
18 different positions at Illumina since then.

19 A. Uh-huh.

20 So then I became director of marketing
21 and -- director of corporate marketing. Excuse me.

22 And then senior director of corporate

1 marketing.

2 And then more recently, chief of staff.

3 Q. When did you become chief of staff?

4 A. August of last year, 2013.

5 Q. When did you become senior director of
6 corporate marketing?

7 A. So that was in 2010.

8 Q. And when did you become director of
9 corporate marketing?

10 A. That was in 2007.

11 Q. Did Illumina undergo a corporate
12 reorganization in 2008?

13 A. In 2008 we added a diagnostics business
14 unit, but that wasn't -- I mean, I wouldn't consider
15 that a corporate reorganization. So the rest of the
16 company structure was not dramatically changed.

17 Q. If a document put out by Illumina on its
18 website, or otherwise public-facing, referred to a
19 corporate reorganization in 2008, would it be
20 referring to the addition of the diagnostics
21 business unit?

22 A. Yes.

1 Q. And nothing else?

2 A. Yes.

3 Q. Do you recall making what we call a
4 "declaration" in this matter?

5 A. Yes.

6 MR. HANKINSON: I'm going to mark this as
7 Exhibit B.

8 (Whereupon, Possemato Exhibit Number
9 B was marked for identification by
10 the Deposition Officer and is
11 attached hereto.)

12 BY MR. HANKINSON:

13 Q. Take a moment and look through Exhibit B,
14 if you would, and confirm for me that this is a copy
15 of your declaration submitted in this case,
16 otherwise, I have to call "shenanigans."

17 (Document reviewed by the witness.)

18 THE WITNESS: Yes, this is it.

19 BY MR. HANKINSON:

20 Q. When did Illumina first hire a chief
21 medical officer?

22 A. So that was Daniel, and --

1 Q. Last name?

2 A. Grosu, G-r-o-s-u.

3 And --

4 DEPOSITION OFFICER: One more time.

5 "G-r-"?

6 THE WITNESS: G-r-o-s-u.

7 DEPOSITION OFFICER: Thank you.

8 THE WITNESS: Yes.

9 And that was -- it was a few years ago.

10 I'm not 100 percent certain of whether it was 2011

11 or whether it was 2010.

12 BY MR. HANKINSON:

13 Q. When did Illumina first hire an in-house
14 regulatory expert, if it ever did?

15 A. So that was quite a while ago.

16 I believe that when Greg Heath joined the
17 company in two -- around the time of the diagnostics
18 business unit department, in 2008; it was shortly
19 thereafter that we hired our first regulatory sort
20 of leader.

21 Q. Did you have any input into a July 2009
22 clinical diagnostics business plan -- portfolio

1 plan?

2 A. No.

3 Q. And who was the regulatory leader that was
4 hired?

5 A. So his first name is Rich; but to be
6 honest, I can't remember his last name. It's been a
7 while.

8 Q. What was the name of the position?

9 A. I believe that it was director of
10 regulatory affairs. But, again, you know, I'm
11 pulling from recall from quite a while ago.

12 And quality -- regulatory and quality, I
13 think it was.

14 Q. Don't roll your eyes at quality.

15 I'd like to refer you to paragraph 3 of
16 Exhibit B, your declaration.

17 A. Okay.

18 Q. And specifically to the second sentence,
19 which runs from page 1 to 2:

20 "More specifically" -- I'm
21 reading from it -- "Illumina
22 develops and sells innovative

1 array- and sequencing-based" --
2 there's a hyphen after 'array'
3 and then a hyphen after
4 'sequencing' -- "solutions for
5 DNA and RNA analysis that serve
6 as tools for disease research
7 and diagnosis, drug development,
8 and for the development of
9 molecular tests in the clinic."

10 Was that an accurate description of the
11 solutions that Illumina offered for sale at the time
12 that you gave your declaration?

13 A. Yes.

14 Q. The next sentence after that states:

15 "Illumina products and
16 services serve life sciences
17 research, applied markets, and
18 the molecular diagnostics market
19 (which is part of the clinical
20 diagnostic market)."

21 Did I read that correctly?

22 A. Yes.

1 Q. What's interesting to me in that sentence
2 is the verb "serve."

3 It's not the same, necessarily, as saying
4 that Illumina sells products to a customer or to a
5 market, and I wonder if that's by design or if you
6 mean "serve" to be synonymous with "sell to."

7 Maybe that doesn't make sense.

8 A. Yeah. I mean, I think they -- they're
9 interchangeable depending on how you think of it,
10 whether you think about serving customers' needs
11 with products that meet those needs or whether you
12 think about selling them something.

13 Q. And you would not be offering any sort of
14 opinion on whether the meaning of "serve" or "sell"
15 is legally relevant; you're just using it in your
16 declaration in a commonsense manner?

17 Do I have that accurately?

18 A. That's right. And, remember, I'm a
19 marketing person, so we serve customers.

20 Q. Up on a platter?

21 A. Right.

22 MR. HORNE: Hey.

1 THE WITNESS: Hey. Some companies, not
2 us.

3 BY MR. HANKINSON:

4 Q. At the time that -- and so, then, when
5 a -- when Illumina is serving a market, it's not the
6 same as serving a customer? A "market" is sort of a
7 broader term?

8 Are you with me so far?

9 A. Yeah.

10 Q. So there's -- you know, Ms. O'Grady this
11 morning used the terms "upstream" and "downstream."

12 And I think you used the term "up
13 front"?

14 Is that what you said when we were talking
15 about Invitrogen products? Something about up front
16 in --

17 A. I had mentioned that sample prep, which is
18 where you pull your nucleic acid out of whatever
19 material that you have, happens up front of actual
20 assays where you're assessing something -- you know,
21 what's in it? How does it react to this?

22 So it was meant just to give you a

1 reference point to that product line.

2 Q. There are certain types of products that
3 are used up front when a laboratory is going to
4 conduct an assay, and certain products that are
5 used -- would those up-front products be considered
6 part of the assay, or are they separate from and
7 occurring prior to it?

8 And pardon my ignorance of the field.

9 A. So are you asking in all cases is that
10 true?

11 Q. Yes, in the way that you're using the
12 language.

13 A. It really depends.

14 Q. So taking the three things that Illumina
15 serves in this sentence -- life-sciences research,
16 applied markets, and molecular diagnostics market --
17 who are the customers that make up life-sciences
18 research?

19 A. So life-sciences research includes a
20 pretty broad spectrum of customers.

21 You know, setting-wise, those customers
22 sit in academic institutes, in government, in

1 research hospitals, in agrigenomics -- which can be
2 a subset of government.

3 There's really sort of a plethora of
4 settings where you might find what we would consider
5 life-sciences research.

6 Q. Pharmacological companies, would they be
7 an aspect of this, or something different?

8 A. Well, yeah, you might consider them --
9 depending on -- on who you are, you might consider
10 them part of the diagnostics market because they are
11 developing drugs.

12 Or you might consider them an applied
13 market because of that -- for that reason.

14 Q. So the four aspects of the life-sciences
15 research that you mentioned, do you think those
16 cover all of the customer settings that are within
17 life-sciences research?

18 A. Well, so those were some examples.

19 Q. Right.

20 A. I mean, if -- if you want -- if you wanted
21 to exhaustively segment the market, it would depend
22 on how you were segmenting it.

1 Q. Uh-huh.

2 A. Those were examples of like the physical
3 locations where you would find -- and in a very
4 general sense.

5 Q. And are there addition physical locations
6 within life-sciences research as you're using that
7 term here?

8 A. So I mentioned the academic institutions,
9 research hospitals, government, agrigenomics.

10 That probably covers a majority of them.

11 Q. So 51 percent -- I mean, so -- it's your
12 term. I'm just trying to understand what it means.

13 A. Yeah. Yeah.

14 Q. Are there more?

15 A. I think that covers much more than
16 51 percent, but I'm just trying to think if I'm
17 missing anything.

18 I think the other -- the other thing would
19 probably include anything in the commercial sector.

20 So those -- those guys, you know, are
21 obviously for-profit entities.

22 There are service labs that fall under

1 that category. There are businesses and biotechs
2 that fall under that category.

3 And there are -- now you need to start
4 crossing over into applied -- but there are all
5 kinds of companies that are looking to discover and
6 do things other than drugs and molecular diagnostics
7 that can use molecular technology.

8 So there's a broader swath for you.

9 That's probably closer to 90 percent.

10 Q. And those are all the physical settings
11 within life-science research that you can remember
12 as you sit here today; correct?

13 A. Yes, that's correct.

14 Q. Let's do the same thing for applied
15 markets. And I don't know if physical settings is
16 still a useful way to list them or if it --

17 A. Yeah.

18 Q. -- should be handled differently.

19 A. No.

20 "Applied" is -- you know, some of these --
21 some of the settings from the life-sciences research
22 side meld over into applied.

1 But when -- when we talk about "applied,"
2 we talk about applications like forensics,
3 agrigenomics in more than industrial sense, public
4 health, population sequencing, consumer genomics,
5 biodefense -- you know, food and water testing.

6 You know, that probably covers at least
7 80 percent of the gamut, at least to the best of my
8 memory.

9 Q. And then there's the molecular diagnostics
10 market.

11 What are the customers that make up that
12 market?

13 A. So these are labs that run tests, and
14 include everything from the large reference labs,
15 like Quest and LabCorp, as an example --

16 DEPOSITION OFFICER: Like what? "Like
17 Quest and" what?

18 THE WITNESS: LabCorp.

19 -- down to smaller clinical labs, CLIA
20 labs, and hospital-based labs.

21 BY MR. HANKINSON:

22 Q. So the way that was said, I couldn't quite

1 tell what was a subset of what. And so --

2 A. Uh-huh.

3 Q. -- I've got, "They are labs that run
4 tests."

5 Was that meant to describe all of the
6 things that came after?

7 A. Yes.

8 Q. And then there are large reference labs,
9 and you used the examples Quest and LabCorp?

10 A. That's right.

11 Q. And then you said there are smaller
12 clinical labs.

13 Were CLIA labs and hospital-based labs
14 intended to be a subset of the smaller, or
15 additional things?

16 A. Yeah. So I mean the point there is that
17 the labs range in size from these larger, very, you
18 know, business-oriented conglomerates, if you will,
19 to individual labs that reside in a hospital setting
20 or that provide services to physicians or to the
21 hospital setting that are more regionally located or
22 smaller.

1 So there's a continuum.

2 Q. And the labs that provide services to
3 physicians in the hospital setting are CLIA labs?

4 A. Some of them are.

5 Q. Some?

6 A. Some of them -- some of them are
7 diagnostics labs where they provide FDA-approved
8 tests in the U.S.

9 Q. As distinct from a lab that is authorized
10 under CLIA to perform its own tests that are
11 certified under CLIA but not approved by the FDA?

12 A. That's right.

13 Q. So we've just covered -- oh. And I'm
14 sorry.

15 Is that all of the customers within the
16 molecular diagnostics market that you can remember
17 here today?

18 A. Yes, I think that describes them.

19 Q. And here it seems like you've got some
20 level of expertise and certainty.

21 I mean, have we covered them all?

22 A. I think that we have covered a good

1 majority of them.

2 Q. I don't like the word "majority" because
3 it means half. Like -- it seems like you probably
4 mean something north of half.

5 A. I do mean something north of half.

6 Q. So are there more that you can remember?

7 A. There's -- no, there's not more that I can
8 remember.

9 Q. And you think that we've come pretty close
10 to being exhaustive in the list of molecular
11 diagnostics market customers?

12 A. I think we've come pretty close to
13 describing all of these and types of customers that
14 reside in them.

15 Q. So now I'd like to go back.

16 And if there's a difference, discuss which
17 of the customers that we just listed out Illumina
18 sold products or services to in 2008.

19 A. Okay.

20 Q. So --

21 MR. HORNE: You mean up to that time or
22 just in 2008 specifically?

1 MR. HANKINSON: Up to 2008, including that
2 whole calendar year.

3 THE WITNESS: Okay.

4 BY MR. HANKINSON:

5 Q. Okay. So in life-sciences research, we
6 have academic institutes?

7 A. Yes.

8 Q. And government?

9 A. Yes.

10 Q. Research hospitals?

11 A. Yes.

12 Q. Agrigenomics?

13 A. Yes.

14 Q. Is it going to be all the ones that you
15 listed?

16 A. I mean, for the most part. And to the
17 best of my knowledge, we've had customers, really,
18 across the whole continuum.

19 Q. In life-sciences research?

20 A. In -- in all of those markets.

21 Q. I guess I'm asking, all of the customers
22 that you listed in all of those markets?

1 A. Yeah. But, I mean -- you know,
2 admittedly, I don't have like a photographic memory
3 of the ledger back prior to 2008 to list all of the
4 customers.

5 Q. Uh-huh.

6 When Illumina added a diagnostic business
7 unit, did it add any customers to the list of its
8 potential customers?

9 A. Do you mean did it add any because of the
10 formation of that business unit or --

11 Q. Yes.

12 A. Yes. I mean, the creation of that
13 business unit was meant to further accelerate our
14 progress against our vision, and -- and that vision
15 is to unlock the power of the genome to improve
16 human health.

17 So yeah, it was -- I mean, it was moving
18 it along that -- that path.

19 Q. Was there a customer that Illumina was
20 going to sell to because it added a diagnostic
21 business unit that it was not selling to before
22 that?

1 A. I don't know.

2 MR. HORNE: I'll just object that that
3 last question was vague.

4 BY MR. HANKINSON:

5 Q. I'd like to refer to paragraph 6 of your
6 declaration.

7 A. Got it.

8 Q. (READING):

9 "Genotyping is often
10 performed using array technology."
11 That's the first sentence, and I'll
12 continue reading:

13 "Array technology generally
14 refers to a collection of
15 microscopic regions of DNA
16 attached to a solid surface.
17 Each region contains a specific
18 DNA sequence known as a probe.

19 "An array is used to
20 determine whether a DNA sample
21 contains the precise DNA sequence
22 that corresponds to the probe on

1 the region.

2 "For example, a sample from
3 a human would be treated and then
4 placed on the array.

5 "The array is then placed
6 into a certain type of machine
7 called a Reader, which can
8 determine whether a certain type
9 of DNA sequence is present in
10 the sample."

11 Then the last sentence of the paragraph
12 is:

13 "This can indicate, for
14 example, the presence of a
15 disease, such as an infectious
16 disease."

17 Did I read that correctly?

18 A. Yes.

19 Q. And the reason that you're discussing
20 genotyping in paragraph 6 is because you're
21 expounding on one of the aspects of Illumina's
22 business; correct?

1 A. Yes.

2 Q. And you explain what genotyping is.

3 That's the purpose of paragraph 6; right?

4 A. Yes.

5 Q. And it discusses an example of a human DNA
6 sequence; right?

7 A. It discusses a human sample -- a sample
8 from a human.

9 Q. Uh-huh. And then determining whether a
10 certain type of DNA sequence is in the sample?

11 A. Right.

12 That DNA sequence, though, could be a
13 microorganism that's in the human sample. It
14 doesn't...

15 Q. And my question is: Specifically, what
16 were the uses of Illumina's products and services,
17 up to and including 2008, where genotyping was used
18 in connection with infectious disease?

19 A. So our technology in 2008 would include
20 sequencing -- because we added that in 2007 -- is
21 capable of detecting sequence from anything with a
22 genome.

1 So we've always had products that address
2 both fixed sets of content. So, you know, for an
3 array, for example, you might put certain probes
4 on it to look for certain things -- disease
5 associations or risks, for example.

6 And then each one of our technologies has
7 the ability for customers to design what probes --
8 this is how you go into DNA and kind of look and see
9 what's there -- to be able to design their own
10 probes.

11 And the sequencing, you can certainly
12 sequence anything that you like.

13 And so a big part of -- of Illumina's
14 technology, how it gets applied, is in customers
15 applying it for their specific need.

16 So, you know, again, like food testing,
17 water testing, public-health applications where
18 you're -- you're able to use things like sequencing
19 to get higher resolution.

20 I mean, in fact, when we first introduced
21 sequencing, because of the level of output that was
22 possible on the systems, smaller genomes, like in

1 microorganisms, were some of the first applications
2 that were used.

3 Q. So in answer to my question, you are
4 listing ways in which customers can use a platform
5 or a technology provided by Illumina that is capable
6 of sequencing in general -- whether it be of human
7 DNA or of other DNA or RNA -- for their own purposes
8 that Illumina does not control.

9 Is that accurate?

10 A. Could you repeat that? I'm not sure I
11 heard that 100 percent.

12 (THE RECORD WAS READ AS FOLLOWS:

13 Q. So in answer to my question,
14 you are listing ways in which
15 customers can use a platform or
16 a technology provided by Illumina
17 that is capable of sequencing in
18 general -- whether it be of human
19 DNA or of other DNA or RNA -- for
20 their own purposes that Illumina
21 does not control.

22 Is that accurate?)

1 THE WITNESS: Not entirely accurate.

2 ///

3 BY MR. HANKINSON:

4 Q. Okay. Please let me know how.

5 A. So -- so it's use of a product that's
6 designed to be used to sequence genomes, de novo
7 genomes, and that includes informatic solutions in
8 many cases to enable that -- I mean, it's
9 intentional.

10 It's not like -- it's not like it's some
11 kind of tech -- tech dev activity that is out in the
12 field that a customer's doing.

13 I mean, by definition, that's what
14 sequencing is, it's the intended product use.

15 The fact that you're -- you're able to
16 leverage it in a fairly ubiquitous way is -- is --
17 you know, it's part of our -- it's part of the
18 vision again.

19 Q. And --

20 A. And that's why we play across so many --
21 sorry -- so many fields.

22 Q. Did you say "informatics" or "infomatics"?

1 A. "Informatics."

2 Q. "Informatics"?

3 A. Right.

4 Q. And could you please define that.

5 A. So "informatics" is the component of
6 analysis that happens after sequencing.

7 So, as you can imagine, sequencing
8 generates a lot of data.

9 You know, our own genome is 3 billion base
10 pairs of data, so there was a time when that was
11 over a terabyte of data.

12 And so using algorithms and analytical
13 tools to be able to extract the answers that you're
14 looking for is a component of our products and
15 solutions.

16 And that is -- that has to be tailored for
17 applications, because it's not the same looking at a
18 microbial genome versus looking at a human genome
19 versus, you know, doing something that's maybe more
20 specifically targeted across a number of samples.

21 It's -- all of these applications require
22 specific informatic solutions on the back end,

1 and -- and then specific library prep solutions on
2 the front end.

3 So these -- these solutions are designed
4 to do what our customers are doing with them.

5 Q. Did you say that the use of the platform
6 would need to be tailored, and that there would be
7 specific informatic solutions on the back end in
8 using Illumina's products with respect to human
9 genetics and with respect to microbial?

10 Those were the two that you mentioned, I
11 believe.

12 A. Well, I used the example of how it's
13 different to analyze a microbial genome than it is
14 to analyze a human genome.

15 Q. Uh-huh.

16 A. But our solutions are -- have specific
17 components to them depending on what we call the
18 "application."

19 So if you're looking at an "applications,"
20 mean if I'm looking at, you know, sort of RNA and
21 transcript domix (phonetic), looking at the
22 composure of RNA in the genome versus I'm looking at

1 whole genome sequencing versus I'm looking at de
2 novo, like sequencing an organism that hasn't been
3 sequenced before, that those all require slightly
4 different informatics approaches.

5 And so --

6 Q. And when you say "I'm looking at this,"
7 "I'm looking at that," it's the customer who's the
8 eye?

9 A. I'm sorry?

10 When I'm saying, "I'm looking"?

11 Q. In your answer you said, "I'm looking at
12 this. I'm looking at that."

13 Were you sort of stepping into the shoes
14 of the customer?

15 A. Yeah. So, you know, when you -- when you
16 look at -- or more even third person than that.

17 When you are looking in general at these
18 spaces, that's what's required to leverage this kind
19 of data.

20 Q. And when you say, "that's what's
21 required," you mean a different back-end
22 informatic --

1 A. You need --

2 Q. -- solution?

3 A. You need solutions. Right. You need
4 solutions.

5 So by definition, sequencing as a
6 technology has a ubiquitousness to it, and it's in
7 assembling solutions for markets that you are able
8 to address many of these different needs.

9 So it's not -- you know, to your question
10 earlier -- that the platform is out there and people
11 are making -- doing tech dev or whatever they're
12 doing on it.

13 MR. HANKINSON: Could I impose upon you
14 to read back the last answer for me.

15 (THAT RECORD WAS READ AS FOLLOWS:

16 Q. You need solutions. Right.

17 You need solutions.

18 So by definition,
19 sequencing as a technology has
20 a ubiquitousness to it, and it's
21 in assembling solutions for
22 markets that you are able to

1 address many of these different
2 needs.

3 So it's not -- you know, to
4 your question earlier -- that the
5 platform is out there and people
6 are making -- doing tech dev, or
7 whatever they're doing on it.)

8 BY MR. HANKINSON:

9 Q. And it's really in designing the
10 particular solutions within what would otherwise be
11 a ubiquitous field of genomics -- or genetic
12 science, that a company provides value to its
13 customers; right?

14 A. No.

15 Q. Okay. So what am I misunderstanding?

16 A. So there's -- there's two components -- or
17 maybe, actually, there's more. Let me just take a
18 step back.

19 So sequencing is a technology. It can be
20 used in many ways, which we talked about.

21 Then there are specific applications that
22 can be delivered to the markets that are more

1 tailored and better suit customers' needs.

2 But sequencing technology and the
3 solutions that Illumina provides, for example, can
4 still be leveraged either in state one, which is a
5 sequencing platform, and you can do things and
6 answer questions with it, or it can be leveraged in
7 solutions.

8 And this -- this really comes into play
9 when you start talking about technology evolution
10 and moving from a research environment into like
11 applied markets.

12 And where, you know, you need to -- an
13 example of a solution is a forensic solution where
14 there's a specific set of things that are needed in
15 order to really completely meet the needs of that
16 customer.

17 Q. Uh-huh. So let me try to identify like
18 some specific examples of the second thing that you
19 said.

20 So you said first, you know, that
21 sequencing is a technology with many different, you
22 know, variants and uses.

1 And then you said, second, there's
2 specific applications that can be developed and
3 delivered to the market that are tailored and then
4 better -- and thus better suited to meet customer
5 needs.

6 I'm right on your one and your two there?

7 A. Well, I didn't say sequencing just as a
8 technology. I mean, there's actually -- so let me
9 try another way of explaining it.

10 So you can purchase a sequencer, and it's
11 a product, and you can do many, many things with it.

12 And then if you're honing into a specific
13 type of an application, you can still do that, but
14 really what you would love to have is this over
15 here, which is a more tailored solution.

16 And so moving in that direction and -- and
17 continuing to refine the technology into those
18 solutions is another component.

19 So this is a product, not just a
20 technology.

21 People have been using those products both
22 in their own applications and -- and in these

1 solutions that Illumina is providing.

2 But they're both products. It's not --
3 "technology" to me implies something that's un- --
4 that's not developed, that's not a complete --

5 Q. Uh-huh.

6 A. -- something that you're selling, you
7 know, that -- it's not ready.

8 Q. The first thing I'll say is you used the
9 word "technology." I didn't make that up. So I'm
10 just trying to understand; I'm not trying to put
11 words in your mouth.

12 A. I think I also said "solution," though.

13 Q. Uh-huh.

14 A. And so maybe it's a -- it's a
15 clarification that when I'm -- I'm trying to
16 describe this to you, it's that both things are
17 actual products and things that are being sold to
18 customers, served up.

19 Q. And that's what I'd like to get to next.

20 A. Okay.

21 Q. So both one and two, in your attempted
22 explanation to me, one being sequencing as a

1 technology -- that is a solution and a product?

2 That's Number 1?

3 A. Number 1 is sequencing, yes.

4 Q. Okay. Number 2 would be a more tailored
5 solution for a specific application that, because
6 it's more tailored would, you know, better suit a
7 particular customer's needs.

8 That's Number 2; right?

9 A. That's correct.

10 Q. Okay. And you said that Number 1 and
11 Number 2 both are products?

12 A. That's right.

13 Q. Okay. So I'd like you to name the
14 products that Illumina made, up to and including the
15 calendar year 2008, in Number 1, sequencing.

16 A. Okay.

17 Q. And in Number 2 --

18 A. Okay.

19 Q. -- the more tailored product.

20 A. Okay. So the BeadLab would be a great
21 example of Number 1. It was a product that was used
22 by leading genotyping centers.

1 An example of a product that would be in
2 Category Number 2 would be the Human-1 Genotyping
3 Beadchip, which is the array that was sold on the
4 BeadStation that had a bioinformatic component to it
5 and generated, then, specific answers related to the
6 content on that array.

7 Q. So those are two specific examples?

8 A. Yes.

9 Q. One from each --

10 A. Yep.

11 Q. -- category?

12 A. Yep.

13 Q. Could you give me more examples, as of the
14 year 2008 or before, for Category 1, sequencing?

15 A. Yes.

16 So, you know, the first platform, the
17 Genome Analyzer in sequencing, which was launched in
18 2007, was for the most part an open platform. It
19 didn't have any, you know, canned applications; the
20 first applications were actually published in
21 customers' hands.

22 Q. What else?

1 A. You want specifically in sequencing? Is
2 that what you asked for?

3 Q. Yes.

4 A. Well, then you're up to 2008, so --

5 Q. Correct. That's it, up to 2008.

6 A. The Genome Analyzer continued to evolve,
7 but it's, you know, for the most part it isn't
8 giving you a new product; right?

9 Q. Okay. And where would BeadXpress fit into
10 these categories?

11 A. So BeadXpress had a combination of both,
12 because BeadXpress could be used in Category 1; it
13 was an open platform.

14 And, in fact, that was one of -- one of
15 its uses. It had this universal bead kit which
16 allowed you to do that.

17 And then there were specific kits and
18 bioinformatics components, too, like the one that
19 was FDA approved, the Factor II and Factor V Leiden
20 tests. That was a packaged FDA-approved solution on
21 BeadXpress.

22 Q. BeadXpress was launched in 2008?

1 A. You know, I don't remember what year it
2 was.

3 Q. The customer who is using a sequencing
4 solution that has a lot of different potential uses,
5 and then is seeking to answer a question or get a
6 solution that's more tailored because it would be
7 better suited to their needs --

8 A. Uh-huh.

9 Q. -- who is that customer?
10 What are the types of customers that would
11 develop that itch for the type two category, these
12 more tailored solutions?

13 A. Yeah. So it's a great discussion of how
14 technology moves from more of a research application
15 into clinical research and into LDTs and then into
16 diagnostics.

17 So the -- the further you go through that
18 continuum into the right, the more of a solution
19 people are looking for.

20 Q. And who are the "people"?

21 A. Well, those groups that I -- that I
22 described.

1 So research labs to clinical research
2 labs to folks doing LDTs. The CLIA labs to
3 molecular diagnostics labs. Those reference labs,
4 hospital labs that we discussed earlier.

5 Q. Was the addition of a diagnostics business
6 unit at Illumina in 2008 helpful in moving, as you
7 say, "to the right" from research to clinical
8 research to CLIA labs using LDTs to diagnostics?

9 A. What do you mean by "helpful"?

10 Q. Was it part of the plan to move Illumina
11 in that direction?

12 A. Oh, yeah. Yes, of course.

13 Q. BeadLab was a customized installation that
14 would be made at a customer's site; correct?

15 A. That's right.

16 Q. And it would cost on the order of a
17 million dollars?

18 A. Yeah, it was in that ballpark.

19 Q. Genome analyzer was a self-standing
20 product that could be sold without a custom install;
21 correct?

22 A. That's right.

1 Q. And that was on the order of 250,000
2 dollars?

3 A. You know, I don't remember the exact
4 price, but I think it was actually a little more
5 than that.

6 Q. And BeadXpress was also a salable unit,
7 not a custom install; right?

8 A. That's correct.

9 Q. And its price point was roughly 98,500
10 dollars; right?

11 A. That's right.

12 Q. If Illumina was -- at any point did
13 Illumina develop, to the order and specification of
14 others, biological or chemical-sensing systems using
15 random array technology to identify inorganic and
16 organic molecules, compounds, and substances?

17 A. I don't know.

18 Q. You're not familiar with any Illumina
19 products that do that -- or services?

20 A. Well, can you read it to me one more time?

21 Q. Sure.

22 Developing to the order and specification

1 of others, biological and/or chemical-sensing
2 systems which use random array technology to
3 identify inorganic and organic molecules, compounds,
4 and substances.

5 MR. HORNE: I'll object to the extent that
6 it calls for a legal conclusion.

7 THE WITNESS: I don't know.

8 BY MR. HANKINSON:

9 Q. That doesn't mean anything to you in terms
10 of product or service that you're familiar with?

11 A. The description does not mean anything to
12 me, no.

13 Q. Did Illumina at any point sell chemicals,
14 namely reagents, for scientific or medical research
15 use for analyzing cells, proteins, nucleic acids,
16 and other molecules of 50 to 10,000 daltons,
17 sequencing DNA, genotyping, gene-expression
18 profiling, and high-throughput screening?

19 MR. HORNE: Same objection.

20 THE WITNESS: Would you read that to me?
21 There was a lot of information in there. If you
22 could read it one more time, that would be

1 helpful.

2 BY MR. HANKINSON:

3 Q. Yes.

4 Did Illumina -- and I'll try to do it with
5 better emphasis instead of getting into the lull of
6 the afternoon.

7 Did Illumina at any time sell chemicals --
8 namely, reagents for scientific or medical research
9 use -- for analyzing cells, proteins, nucleic acids,
10 and other molecules of 50 to 10,000 daltons,
11 sequencing DNA, genotyping, gene-expression
12 profiling, and high-throughput screening?

13 So chemicals for that stuff.

14 A. So we sell reagents --

15 MR. HORNE: Same objections.

16 Go ahead.

17 THE WITNESS: -- that analyze the nucleic
18 acids. And -- and we have sold reagents that
19 analyze proteins and other things for those
20 applications.

21 The "50 to 10,000 daltons" thing, I
22 can't -- I can't confirm that.

1 BY MR. HANKINSON:

2 Q. That would be something more specific than
3 you're familiar with?

4 A. Yeah.

5 Q. And the reagents that you are mentioning,
6 what is the name of those products?

7 A. So there are -- there are -- are you
8 talking about now through the company's history or a
9 specific time frame or a specific set of products?

10 Q. Each reagent or other chemical that
11 answers that description that you're aware of.

12 A. Okay. So all of our platforms have
13 reagents that run on them, so there are thousands of
14 SKUs in our catalog.

15 Q. "S-K-U"?

16 A. Yes.

17 So there are thousands of catalog numbers
18 related to those different reagents. There are
19 product families, such as Nextera and TruSeq and
20 GoldenGate genotyping that describe the general
21 areas of those that work on the systems.

22 But I would be remiss to tell you that I

1 could name all of -- all of them.

2 Q. But generally they are products to be used
3 upon platforms?

4 A. That's correct.

5 Q. And the platforms are to be used in
6 sequencing and -- well, in any event, the machines
7 that Illumina manufactures for the customer's use?

8 A. Right. The reagents are used on the
9 platforms.

10 Q. And, then, to your knowledge, has Illumina
11 ever sold the service of scientific and medical
12 research; namely, the analysis of cells, proteins,
13 nucleic acids, and other molecules of 50 to 10,000
14 daltons, sequencing DNA, genotyping, gene-expression
15 profiling, and high-throughput screening?

16 MR. HORNE: Object to the extent it calls
17 for a legal conclusion.

18 THE WITNESS: So Illumina also offers
19 services, both genotyping and sequencing services.

20 BY MR. HANKINSON:

21 Q. And what are those services branded as?

22 A. FastTrack genotyping services, FastTrack

1 sequencing services, and TruSight.

2 We have a CLIA lab that provides --

3 DEPOSITION OFFICER: I can't hear you.

4 THE WITNESS: I'm sorry.

5 DEPOSITION OFFICER: "We have a CLIA lab
6 that provides..."?

7 THE WITNESS: We have a CLIA lab that
8 provides whole-genome sequencing services, and
9 another lab that provides non-invasive prenatal
10 testing services.

11 BY MR. HANKINSON:

12 Q. Is that a CLIA lab?

13 A. Yes.

14 Q. Was TruSight the name of the CLIA lab
15 service?

16 A. TruSight is a specific name of one of the
17 tests.

18 Q. And that's T-r-u, and then the word
19 "sight" is S-i-g-h-t?

20 A. That's correct.

21 Q. One word?

22 A. That's correct. Yes, one word.

1 Q. And that test is done at the CLIA lab?

2 A. The TruSight test is done at our CLIA lab
3 in San Diego, yes.

4 Q. Is FastTrack still offered?

5 A. FastTrack services are still offered,
6 yes.

7 Q. And to take advantage of these services,
8 something is sent to those CLIA labs, like a sample?
9 Is that accurate?

10 A. Yes, a sample.

11 Q. And then the CLIA lab does what it does.
12 And what is its output? What do they give back?

13 A. So in the case of TruSight, which I think
14 you're referring to, they -- they -- they return a
15 report, a clinical report.

16 Q. And what about the other scientific and
17 medical research services that Illumina offers, what
18 is the output of those?

19 A. So for the non-invasive prenatal testing
20 service, it's also a record. Because, again, it's a
21 lab-developed test, an LDT, so that would be what
22 you would get.

1 And then for the FastTrack services, it's
2 data files, analysis, consultation with one of our
3 services scientists. So it's a much more tailored,
4 customized thing.

5 Q. A report?

6 A. Delivery of value. I mean, because it
7 includes a report and -- and some consultation and
8 phone calls back and forth, and other things as
9 well -- data -- a data file, you know?

10 Q. Is TruSight offered anywhere outside of
11 Illumina's CLIA lab?

12 A. Not that I'm aware.

13 Q. Is "reagent" a molecular assay or is it
14 something different?

15 A. It is different.

16 Q. And what are the differences between the
17 two?

18 A. Yeah. So when we refer to a "reagent" in
19 our space, we're usually referring to an
20 individual -- like a buffer bottle, a buffer -- you
21 know, Buffer A.

22 Reagents are the set of things that go

1 into an assay or into a sample preparation.

2 So when you refer to an assay, you're
3 usually referring to something that gives you some
4 form of an answer, whether that's a report or
5 whether that's data.

6 Q. It seemed like you trailed off. Are you
7 finished with your answer?

8 A. I am. I'm finished, yeah.

9 Q. Has Illumina ever sold scientific
10 equipment and instruments; namely, scanners,
11 hybridization stations, and fluidics delivery and
12 computer systems sold as a unit, and cassettes
13 containing molecular sensing optical-fiber bundles
14 for analyzing cells, proteins, nucleic acids, and
15 other molecules of 50 to 10,000 daltons, sequencing
16 DNA, genotype, gene-expression profiling, and
17 high-throughput screening?

18 MR. HORNE: Compound, lacks foundation.
19 Object to the extent it calls for a legal
20 conclusion.

21 THE WITNESS: Yes.

22 BY MR. HANKINSON:

1 Q. And what are those that it sells?

2 A. So the -- the one -- the bit of that that
3 resonated that -- the fiber-optic bundles that you
4 were describing was our Sentrix Array Matrix, which
5 was used for GoldenGate genotyping.

6 DEPOSITION OFFICER: "Which was used for
7 GoldenGate"?

8 THE WITNESS: "GoldenGate" -- yes.
9 Sorry -- "genotyping."

10 I forget that some of these words are not
11 like normal words people use.

12 BY MR. HANKINSON:

13 Q. And GoldenGate is not offered anymore?

14 A. We -- yeah, we're recently going through
15 the process of retiring it, yeah.

16 Q. And the Sentrix Array Matrix, can you
17 describe its relationship to whatever GoldenGate
18 genome typing is?

19 A. Yes.

20 So the Sentrix Array Matrix, the
21 fiber-optic bundles that you described in that very
22 lengthy description, were -- are basically -- if you

1 looked at the Sentrix Array -- Sentrix Array Matrix,
2 it's about the size of a large piece of toast, and
3 it had 96 pins that would stick up from it.

4 And within each of those pins there were
5 fiber-optic bundles on which beads resided. Those
6 beads carried nucleic acids -- probes -- that were
7 used to assay -- what we've talked about -- various
8 DNA samples. And that was used -- that's the
9 genotyping application.

10 And so, you know, the relationship of the
11 Sentrix Array Matrix to GoldenGate is it was what we
12 would call the substrate. So you do the assay on
13 the substrate, if that makes sense.

14 Q. Is GoldenGate the name of a machine or
15 something else?

16 A. No, it's the name of an assay.

17 Q. Go ahead and please explain further.

18 A. So the GoldenGate assay is the biochemical
19 way by which those probes that I described bind to
20 the DNA and then get read.

21 So it's -- it's the -- the means
22 scientifically by which the answers get generated --

1 Q. Uh-huh.

2 A. -- if that -- if that makes sense.

3 Q. And did Illumina at any point sell a
4 product in which that GoldenGate assay subsisted --
5 you know, worked, functioned?

6 A. So we had many products where GoldenGate
7 was used. I mean, very successfully for years. The
8 BeadLab used GoldenGate.

9 Its desktop little sister, the
10 BeadStation, used GoldenGate.

11 Q. How much was a BeadStation, in money?

12 A. BeadStation was about a quarter of a
13 million.

14 Q. Okay. And you were listing the products
15 in which the GoldenGate was used.

16 A. Yeah.

17 So it might be helpful just to note
18 that -- so each of the systems where genotyping was
19 doable with an array technology, we would use
20 GoldenGate.

21 So assays are interchangeable on
22 systems.

1 Q. Could you just repeat exactly what you
2 said again.

3 A. So each of the systems for -- for arrays
4 that could use this technology, used GoldenGate.

5 And so it's important to note that assays
6 can be interchanged on the system.

7 So there's another assay called Infinium
8 that could also be used on the BeadStation.

9 So this comes -- this comes back to the
10 point earlier about the -- the solution in its more
11 open configuration.

12 So I don't know if that helps.

13 Q. Maybe.

14 So what you're saying is that the desktop
15 BeadStation would use GoldenGate, but it might also
16 use other assays?

17 A. That's correct.

18 Q. And was the same true of BeadLab?

19 A. BeadLab was primarily a GoldenGate
20 genotyping system.

21 Q. And what are the other machines or systems
22 that would use the GoldenGate assay?

1 A. It was primarily -- it was primarily those
2 two.

3 There was another scanner that came after
4 BeadStation; that was iScan. And -- but I can't
5 remember whether GoldenGate was actually -- I don't
6 think it was actually usable on that system.

7 Q. So what we've been discussing, GoldenGate
8 was -- or subsisted in cassettes containing
9 molecular-sensing optical-fiber bundles --

10 A. That's right.

11 Q. -- right?

12 A. Yeah.

13 Q. Were there any other cassettes containing
14 molecular-sensing optical-fiber bundles that you're
15 aware of Illumina selling?

16 A. No.

17 Q. So let's turn to the -- are you aware, at
18 any point, of Illumina selling scanners,
19 hybridization stations, and fluidics delivery and
20 computer systems sold as a unit?

21 A. Yes.

22 Q. And what products did Illumina sell that

1 fit that description?

2 A. So it was primarily the BeadLab and the
3 BeadStation, and then potentially also iScan.

4 But, you know, the hybridization stations
5 were something we were, you know, gradually trying
6 to simplify and remove.

7 So I just don't know whether iScan had
8 them or not.

9 They are array technology, essentially.

10 Q. Oh, these are all types of array
11 technologies?

12 A. These -- these are all systems that
13 support microarrays -- microarray-based genetic
14 analysis.

15 Q. And is a microarray the same thing as a
16 molecular assay?

17 A. A microarray is a meth- -- a method.

18 A molecular assay is a type of assay.

19 So yes, it's a method that can be used for
20 a molecular assay, if that makes sense.

21 Q. But microarray is not the product; the
22 system that supports the microarray is the product

1 that Illumina sells?

2 A. Right. So the product is the system, plus
3 the reagent kits -- or, you know, the GoldenGate kit
4 that you would use with it --

5 Q. Uh-huh.

6 A. -- as well as the substrate.

7 So the Sentrix Array Matrix that we talked
8 about earlier, those things together would be what
9 you would need to use it in the case of arrays.

10 Q. And to use the items that you just
11 mentioned for a microarray -- which is the only
12 thing they're used for; right?

13 A. Those -- these three items that I just
14 described, yes, are microarray.

15 Q. They're the systems and components to
16 support microarray?

17 A. They are the systems and components to
18 support a microarray-based analysis; that's
19 correct.

20 Q. And that is those systems and components
21 only use, right, is to support microarray
22 analysis?

1 A. Yes.

2 Q. To be able to use those three things to do
3 a microarray analysis -- I'm going to ask the
4 question kind of colloquially to try to communicate
5 better, and then maybe more specifically.

6 Like to use those three items that you
7 mentioned to do a microarray analysis, who do I have
8 to be? By which I mean, like I know I couldn't do
9 it right now.

10 A. You could if you were trained.

11 Q. If I was trained. Very nice.

12 And so I guess that's where I'm trying to
13 get.

14 Like what kind of training would I need
15 for this to be useful to me or for me to even --
16 yeah, for this to be useful to me?

17 A. So you would need basic laboratory skills,
18 and then you would -- you would typically -- I mean,
19 all of our customers are trained by Illumina field
20 applications folks, so...

21 Q. And then a separate question: What
22 education or background would I need to be

1 interested in the answer --

2 A. Uh-huh.

3 Q. -- that a microarray analysis -- using
4 those three items that you mentioned -- can
5 provide?

6 A. So I mean, I think -- the first part was
7 what? Discipline? Is that what you asked?

8 I'm sorry. Say the first part.

9 What kind of what would I have to be?

10 MR. HANKINSON: I won't do it better, so
11 could we try to read it back.

12 (THE RECORD WAS READ AS FOLLOWS:

13 Q. And then a separate
14 question: What education or
15 background would I need to be
16 interested in the answer --

17 A. Uh-huh.

18 Q. -- that a microarray
19 analysis -- using those three
20 items that you mentioned --
21 can provide?)

22 THE WITNESS: Yeah. So I mean, as to

1 education or background, I think it's more if I'm --
2 if I'm in a setting where I am interested in using a
3 molecular approach, so I'm interested in
4 understanding the genetic etiology of something,
5 then I would be interested in using the technology.

6 So I don't know if that's predicated
7 necessarily on education or background.

8 BY MR. HANKINSON:

9 Q. So someone who is interested in a
10 molecular approach and is interested in molecular
11 etiology, e-t-i-o-l-o-g-y?

12 A. Yeah.

13 Q. And what is "etiology"?

14 A. It's what's going on molecularly.

15 So if I'm interested in -- in the
16 genetics, let's say, as a simpler way of just -- you
17 know, I think that there is something to understand
18 in the DNA or RNA.

19 Q. This is someone who wants to know what's
20 going on with the DNA or RNA sequence?

21 A. Or to screen something that's already
22 known and look to see if it's there.

1 Q. In a high-throughput way?

2 A. No, not necessarily.

3 Q. Not necessarily.

4 A. Yeah.

5 Q. Would a treating physician purchase the
6 three items that you mentioned to do microarray
7 assays in treating patients on an individual
8 basis?

9 A. Today?

10 MR. HORNE: Lacks foundation.

11 BY MR. HANKINSON:

12 Q. If it changed over time, I'd like to know
13 the answer and how it changed over time.

14 A. Well, those three, because we're
15 obsoleting that product, they are not available
16 today, so they would not be ordering it.

17 Q. At the time that they were available.

18 A. At that time that they were available, I
19 mean, physicians don't typically run their own
20 tests, at least not -- not that I'm aware.

21 I mean, that said, there are clinicians
22 that are actually -- have a research lab as well as

1 a clinical practice, and so if I were one of those
2 people, then yes. Those are the MD/Ph.D people that
3 spend way too much time in school.

4 Q. "MD" what?

5 A. MD/Ph.Ds. Yes, there are such people out
6 there.

7 Q. Oh, my.

8 So like a MD/Ph.D might have a lab that's
9 a research lab and a clinical lab?

10 A. They'll have a clinical practice. So
11 they'll be seeing patients, but they'll also be
12 doing research on something, probably their area of
13 interest.

14 You know, if I'm an oncologist and I'm
15 also doing oncology research, or I'm a psychiatrist
16 and I'm also doing Alzheimer's research or...

17 Q. So the subset of treating physicians who
18 are doing this kind of microarray would be highly
19 educated people, these MD/Ph.Ds?

20 A. Yeah, I think MD/Ph.Ds, by definition, I
21 think, are highly educated.

22 Q. Those are the types of treating physicians

1 that would be using microarrays at the time that
2 these products were offered?

3 A. So I think those are the type of people
4 who would be likely to order something like that as
5 a product, but --

6 Q. Fair enough.

7 A. Right.

8 Q. Do you know what a chief of pathology
9 is?

10 A. Yes.

11 Q. And what does a chief of pathology do?

12 A. So a chief of pathology, in my
13 understanding, is -- oversees a pathology
14 department, whether it's in a hospital or another
15 setting, and calls the shots in that group, how they
16 do things, what they offer.

17 Q. And is that the same person who is the
18 head of a research lab who also has a clinical
19 practice, or is that a different --

20 A. No --

21 Q. -- person?

22 A. -- not necessarily.

1 So pathology -- I mean, these guys are the
2 folks that are looking at what's going on in the
3 sample, whether it's known genetic variation or, you
4 know, some kind of a change -- oncology genetic
5 disease.

6 That's a different category of -- of
7 clinician.

8 MR. HANKINSON: Is this a good time for a
9 break?

10 MR. HORNE: Sure.

11 DEPOSITION OFFICER: Off the record.

12 (Whereupon, a recess was held
13 from 3:51 p.m. to 4:11 p.m.)

14 DEPOSITION OFFICER: Back on the record.

15 (Whereupon, Possemato Exhibit Number
16 230 was marked for identification by
17 the Deposition Officer and is
18 attached hereto.)

19 BY MR. HANKINSON:

20 Q. I'm going to hand you what's been marked
21 as Exhibit 230.

22 (Document reviewed by the witness.)

1 BY MR. HANKINSON:

2 Q. Is Exhibit 230 the result of a search that
3 you entered into GenomeWeb?

4 A. Yes.

5 Q. What date did you enter the search on?

6 A. Two weeks ago, so it was 11/5.

7 Q. Do you know what algorithm GenomeWeb uses
8 for searches?

9 A. No.

10 Q. Are all of the search results that you got
11 for Illumigene in the links that are listed in
12 Exhibit 230 related to Meridian Bioscience?

13 A. They appear to be. There are some that
14 are related to others, and you can clearly see which
15 ones those are.

16 There's one at the end that's related to
17 Cepheid.

18 Q. I'm seeing Meridian.

19 A. On the last page, "On Heels of FDA
20 Approval" --

21 Q. Yes.

22 A. -- "Cepheid's Expert Test Performs Well in

1 Multi-Center Clinical Study."

2 Q. And the hit that is in bold under that
3 one --

4 A. Is Illumigene.

5 Q. -- is Illumigene; correct?

6 A. Right.

7 But Meridian is not mentioned there; the
8 name "Meridian" is not mentioned there.

9 Q. Do you contend that the reference to
10 Illumigene is anything other than a reference to
11 Meridian's Illumigene?

12 A. No, no. I don't know specifically. But
13 it was just in response to your question about
14 whether all of them pertained to Meridian.

15 I didn't click on that link.

16 MR. HANKINSON: I'd like to give you
17 what's been marked as Exhibit 206.

18 (Whereupon, Possemato Exhibit Number
19 206 was marked for identification by
20 the Deposition Officer and is
21 attached hereto.)

22 BY MR. HANKINSON:

1 Q. Exhibit 206 is dated November 1st, 2013;
2 right?

3 A. I don't know. Give me a minute.
4 Say that one more time, please.

5 Q. The date of Exhibit 206 is November 1st,
6 2013?

7 A. The date of that release, yes.

8 Q. And the release is about "Verinata
9 Health's Verifi Prenatal Test"?

10 A. Yes.

11 Q. Is that accurate?

12 A. Yes.

13 Q. The first sentence of this release states:

14 "Illumina, Inc.,
15 (NASDAQ:ILMN) today announced
16 that the Verifi Prenatal Test,
17 offered by Verinata Health, an
18 Illumina company, will be
19 available to pregnant women in
20 California through the state's
21 Prenatal Screening Program."
22 Did I read that right?

1 A. Yes.

2 Q. Did Illumina acquire Verinata Health at
3 some point?

4 A. Yes.

5 Q. Did Verinata Health retain its business
6 name after the acquisition?

7 A. It was called -- no. It was called
8 "Verinata, an Illumina Company."

9 Q. So after the acquisition, it was referred
10 to as "Verinata," comma, "an Illumina Company"?

11 A. I don't think the comma was there. I
12 mean, it was in the logotype, but I guess if you
13 wrote it out, it would probably be used that way.

14 Q. And the brand name of -- and did the
15 Verifi Prenatal Test exist prior to the
16 acquisition?

17 A. Yes.

18 Q. And it retained its brand name, Verifi,
19 after the acquisition?

20 A. Yes, the service name was decided to be
21 kept.

22 MR. HANKINSON: I'd like to direct your

1 attention to what's been previously marked as
2 Exhibit 54.

3 (Whereupon, Possemato Exhibit Number
4 54 was marked for identification by
5 the Deposition Officer and is
6 attached hereto.)

7 BY MR. HANKINSON:

8 Q. Are you familiar with a company called
9 "Luminex"?

10 A. Yep.

11 Q. Is that a competitor of Illumina?

12 A. It is another assay methodology that's out
13 in the market.

14 Q. Is that different from being a
15 competitor?

16 A. Yeah. I mean, because their technology
17 has different applications than ours does in certain
18 areas, so we don't -- we don't really regard them as
19 one of our top competitors.

20 Q. Or a competitor at all?

21 A. Well, I mean, I guess to some extent we
22 will -- we will overlap or do overlap, but it's not,

1 you know, someone we focus on.

2 Q. And I'm sorry. I'm just asking if it's a
3 competitor or not, and I'm not getting an answer.

4 A. When I was in marketing, we didn't really
5 consider them a competitor, but perhaps some of the
6 businesses consider them a competitor today. I
7 wouldn't know.

8 Q. Some of businesses within Illumina?

9 A. Some of the business units within Illumina
10 could.

11 Q. And when were you in marketing?

12 A. Well, remember, I left August of last
13 year.

14 Q. And why did you not consider them a
15 competitor?

16 A. Again, because the -- the types of
17 offerings that they had were of different -- for
18 different applications, different complexities, so
19 there was minimal overlap for us.

20 So they weren't showing up where we were
21 showing up in the field.

22 Q. Under that definition, then, Meridian is

1 not a competitor of Illumina. Would that be
2 accurate?

3 A. Well, again, when I was in marketing, we
4 didn't focus on Meridian, so I don't know whether
5 one of the business units today would consider them
6 a competitor.

7 Q. But to the same extent that your answer is
8 that Luminex is not a competitor, that applies to
9 Meridian as of the time that you were in
10 marketing?

11 A. It's exactly the same in the sense that
12 when I was in marketing, we didn't focus on them as
13 a competitor, but whether the business units today
14 is -- we have different focus, new business units.
15 Whether they consider them a competitor, I just
16 don't know.

17 Q. Yeah. I'm just talking about up through
18 2013 when you left marketing, when you did know. So
19 can we focus on that time frame?

20 A. We did not focus on them as a competitor
21 in our marketing activities.

22 Q. And why when I ask, "Are they a

1 competitor?" do you keep saying, "We did not focus
2 on them in our marketing as a competitor" instead --

3 A. I -- I --

4 Q. -- of just answering "Yes" or "No"?

5 A. Because I don't know whether product
6 marketing or other folks of the company, in general,
7 would consider them a competitor.

8 Q. But you personally did not?

9 A. I personally did not.

10 Q. And for the same reasons that you
11 personally did not feel that Luminex was a
12 competitor at the time?

13 A. Right. Because we were not focusing on
14 them in our marketing activities or tactics.

15 Q. Now, you gave a different reason before
16 about why Luminex was not considered a competitor by
17 you at the time, which had to do with it having
18 different levels of complexity --

19 A. And there's --

20 Q. -- and --

21 A. And there's different --

22 Q. -- and not showing up in the same place.

1 A. And there's different overlap, right.

2 Q. So --

3 A. This would have been more of a competitor
4 back when BeadXpress was in the market. It's a
5 lower-complexity platform.

6 The whole-genome sequencing is 3 billion
7 base pairs; this is like 100 snips. It's just
8 different. They are complementary technologies.

9 Q. Which are complementary technologies?

10 A. Something that does 100 genetic variants
11 versus something that assesses across a genome or
12 assesses thousands of things across a genome.

13 Q. Correct me if I'm wrong, but you said
14 something along the lines of "They are different
15 levels of complexity so they weren't showing up in
16 the same places"?

17 A. Yeah. So we weren't competing for a sale
18 of a sequencer with a Luminex xMAP system.

19 Q. And what were the reasons that you were
20 not competing with them for the sale of a -- what
21 did you say?

22 A. This system that's listed here, the xMAP

1 system (indicating).

2 Q. Uh-huh.

3 A. So it's -- they have an assay system.

4 And you might note that they -- they do
5 similar applications -- genotyping, gene expression.

6 But if you look at their systems, if you
7 go to some of these additional pages, you can see it
8 says "50 tests in one reaction, a couple hundred
9 tests in one reaction."

10 And if you were to draw a parallel, our
11 system tests 3 billion base pairs in one reaction --

12 Q. Oh, my word.

13 A. -- or 100,000, you know, tests in one
14 reaction.

15 So they are complementary technologies in
16 that, you know, a customer might have them both in
17 the lab because for certain applications the lower
18 complexity, the 50 to 100, works.

19 And then for other applications, the whole
20 genome, the sequencing 100,000, 3 billion base pairs
21 works.

22 And so you're not really competing with

1 them because of that reason.

2 Q. And what did you mean when you said, "They
3 are not showing up in the same place"?

4 A. So they're not showing up in the same
5 sale. You know, they're not -- we're not competing
6 with them because it's -- we're -- we're selling
7 apples and oranges. They're not another apple.

8 Q. And you're selling apples and oranges
9 because of the comparison between the 100 or 200
10 level of multiplexing versus the 100,000 level of
11 multiplexing?

12 A. Yeah, exactly. I mean, these are the same
13 people -- people doing molecular biology and using
14 applications like genotyping and gene expression.

15 Q. Yeah.

16 A. But at one end of the spectrum versus the
17 other, there are different systems that -- that do
18 those things, so you -- often you do both.

19 Q. So if there was a product offering that
20 was from Luminex, and it was on the level of
21 100,000 -- and -- I'm sorry. I'm losing track of
22 the terminology.

1 A. Yeah.

2 Q. But the multiplexing is on the level of
3 100,000 -- how would you phrase that?

4 A. Yeah, so it's a higher-complexity assay.

5 Q. A higher-complexity assay --

6 A. Yeah.

7 Q. -- meaning that there are many more base
8 pairs being tested at the same time?

9 A. Yeah, many more, you know, sort of
10 differences in the genome being tested at the same
11 time.

12 Q. At the same time.

13 Then that would be apples to apples.

14 A. Yeah, it would probably become more of an
15 issue, and it would be more of a -- seen as more of
16 a competitor.

17 Q. And in contrast, the "apples to oranges"
18 is when you're comparing something on the level of
19 100,000 to something on the level of 100 or 200?

20 A. Yeah.

21 Q. So then it would be even more of a
22 completely different thing, even farther apart than

1 apples and oranges if you were talking about a level
2 of complexity of one?

3 A. Well, it's very similar to this.

4 Q. "This" meaning?

5 A. The Luminex technology.

6 Q. So even farther --

7 A. So it's not as lower complexity.

8 Q. But even farther away from the apple,
9 which would be --

10 A. 100,000.

11 Q. Offered by Illumina?

12 A. That's right. I mean, it's -- it's a
13 different complexity assay.

14 Q. Which is as different as apples and
15 oranges?

16 A. It's very different and, again,
17 compatible; right?

18 You would have both in the same lab.
19 In -- in all likelihood, you would have them both in
20 the same place, because you would have applications
21 on both types of technology.

22 Q. At some point did Illumina begin to market

1 diagnostic solutions under the brand name "Illumina
2 Dx"?

3 A. Yes.

4 Q. About when was that?

5 A. Well, Mickie had championed that, and she
6 joined, I think --

7 Q. Ms. Henshall?

8 A. Ms. -- yes, Mickie Henshall.

9 And she championed that. It was after
10 the -- the BeadXpress launch. So it would have been
11 somewhere between 2006, 2008, but that brand
12 strategy was worked up, and you started to see
13 Illumina Dx.

14 Q. And would it be accurate -- you started to
15 see Illumina Dx internally. And then when did that
16 become external facing?

17 A. Well, when BeadXpress was launched, there
18 were -- there was an intention to put it out there.
19 I don't know exactly when the first thing showed up.

20 Q. The first thing being use of Illumina --

21 A. The first --

22 Q. -- Dx?

1 A. -- external use; that's right.

2 DEPOSITION OFFICER: You have to take
3 turns, please. Please wait for him to finish. You
4 are both talking at the same time.

5 THE WITNESS: I'm sorry. I'm so sorry.

6 DEPOSITION OFFICER: That's okay.

7 (WHEREUPON, A DISCUSSION WAS HELD
8 OFF THE RECORD.)

9 THE WITNESS: So when the first time it
10 showed up externally happened, I just couldn't
11 recall, you know --

12 BY MR. HANKINSON:

13 Q. Uh-huh.

14 A. -- but it was right around or after that
15 time of launch.

16 Q. And at that time -- whenever it was,
17 whether it was 2008 or 2009 --

18 A. Yeah.

19 Q. -- Illumina Dx would be a brand that was,
20 as you were saying, complementary to products
21 offered by Luminex?

22 A. So Illumina products, in general, being of

1 a higher complexity, are complementary to other
2 lower-complexity technologies like -- like Luminex.

3 BeadXpress was a competitor to Luminex
4 direct, like, you know, because it's in the same
5 complexity level, 0 to 96.

6 So some of these systems listed here in
7 this exhibit were being -- they were trying to sell
8 them to the exact same customers under the exact
9 same, you know, sales situation.

10 Q. I was hoping to kind of do this more
11 generally, but let's talk about time frames and how
12 things changed over time.

13 A. Okay.

14 Q. So you've got Luminex as a company, and
15 you have Illumina as a company.

16 And in 2008 BeadXpress launches; right?

17 A. Yes. Sorry. Yes. I'm nodding.

18 Q. In 2008 when BeadXpress launched, Luminex
19 was already in the market with what product that
20 competed with BeadXpress?

21 A. You know, I'm -- I'm not certain what
22 products they had in the market at that time, but I

1 believe their xMAP system was in the market at that
2 time.

3 Q. And that it was a product that competed
4 with BeadXpress?

5 A. Right. That's correct.

6 It -- it was a very similar product with
7 similar complexity and applications.

8 Q. And at some point, either in 2008 or 2009,
9 BeadXpress was one of the solutions marketed under
10 Illumina Dx.

11 Is that what you're saying?

12 A. Say that one more time.

13 Q. In 2008 or 2009, at some point, BeadXpress
14 became a solution marketed under the brand Illumina
15 Dx.

16 Is that what you're saying?

17 A. I'm saying that BeadXpress was -- was --
18 it was always marketed under the Illumina brand, but
19 we had this sub-family that was Illumina Dx.

20 I mean, when you look at brand strategy,
21 that's what was going on.

22 Q. In 2008 or 2009, at some point, Illumina

1 Dx became external facing; right?

2 A. That's correct.

3 Q. And at that time it had applicability to
4 BeadXpress; right?

5 A. Yes.

6 Q. And at that same time, the Luminex xMAP
7 system was still available in the market; right?

8 A. I believe so. I don't know that for
9 certain, yes.

10 Q. So at that time -- and what was your role
11 at that time?

12 A. I was -- I think at that time I was
13 director of corporate marketing.

14 Q. Did part of your role have to do with
15 branding?

16 A. Yes.

17 Q. At that time, did you find the marketing
18 of a similar product with a similar application from
19 Luminex to be confusing with a similar product with
20 a similar application from Illumina Dx?

21 A. Why would it be confusing?

22 I'm sorry? I don't -- maybe I don't

1 understand the question.

2 Q. Why would it not be confusing?

3 A. There are many products that out there
4 that, you know, when you launch a product, might
5 have similar attributes.

6 I mean, that's just competitive selling.

7 So that's why I think maybe I don't
8 understand the question.

9 Q. So it would be even less likely to be
10 confusing, in your opinion, if the products did not
11 have similar attributes?

12 A. I'm just not sure what -- what you're
13 pointing to as confusing.

14 Q. I'm not. I'm asking a new question.

15 A. Oh, okay. Can you ask it one more time?
16 I'm sorry. I'm just not understanding.

17 Q. Sure.

18 When I was asking about whether you found
19 it confusing, you said, "I don't know why you're
20 asking whether it's confusing. There are often
21 similar products with similar attributes available
22 on the market."

1 And so I guess I'm trying to say, in your
2 opinion, it takes something more than having similar
3 products with similar attributes to be confusing?

4 A. Yeah.

5 MR. HORNE: Vague.

6 THE WITNESS: Yes.

7 BY MR. HANKINSON:

8 Q. And there are two names that I am
9 referencing: Luminex and Illumina Dx.

10 A. Okay.

11 Q. And you're saying, "I find them so much
12 not confusing that I don't understand the nature of
13 your question."

14 MR. HORNE: Misstates testimony.

15 THE WITNESS: I -- I don't find it
16 confusing that there would be two products with
17 similar attributes on the market.

18 Now, if you're asking the names and
19 whether those are confusing, I think they're very
20 different brand names.

21 I mean, you have a company name over
22 which -- Illumina has a monolithic brand name which

1 overshadows all products; and then you have the
2 Luminex brand name, which they really weren't
3 positioning in quite the same way.

4 So they have more of a partnering
5 strategy. It was more like the "Intel inside" a
6 little bit.

7 So there wasn't -- there wasn't this
8 confusion. It's all about positioning. So I guess
9 the market understood the difference, and so it
10 wasn't a con- -- a point of confusion for
11 customers.

12 BY MR. HANKINSON:

13 Q. You just said, "I guess the market
14 understood the difference."

15 A. I guess --

16 Q. Did I get that right?

17 A. I guess my point is that the market seemed
18 to understand the difference.

19 Q. What is your basis for saying that?

20 A. My basis for saying that is, you know, we
21 didn't get any issues elevated to us from our sales
22 reps saying that they were -- I mean, certainly they

1 were competing in BeadXpress sales with Luminex.

2 But, you know, there wasn't any kind of
3 up -- uproar about that it was a branding issue.

4 And, you know, with -- either it could be
5 because Illumina -- I mean, Illumina, with our
6 branding strategy and -- and with the "Illumi"
7 prefix.

8 There's been an awful lot of focus on the
9 "i," and you note in our logo it's pumpkin.

10 And there's, you know, the Illumina
11 Community and Illuminotes and dah, dah, dah, dah.

12 So the association there, I think, we've
13 done a good job of reinforcing it, so there wasn't a
14 confusion between Illumina Dx and Luminex.

15 Q. When you said that it seemed the market
16 understood the difference, and I asked what your
17 basis was, you said that "No issues were elevated to
18 us from sales reps, no kind of uproar about it being
19 a branding issue."

20 Were there no reports of customers being
21 confused between the two?

22 A. No reports that I'm aware of.

1 MR. HANKINSON: I'd like to refer you to
2 Exhibit 214.

3 ///

4 ///

5 (Whereupon, Possemato Exhibit Number
6 214 was marked for identification by
7 the Deposition Officer and is
8 attached hereto.)

9 BY MR. HANKINSON:

10 Q. Take a moment to familiarize yourself with
11 Exhibit 214, and then please also look at paragraph
12 40 of your declaration, which is Exhibit B.

13 A. Paragraph 40?

14 Sorry.

15 Q. Yes.

16 A. Okay. Thank you.

17 Q. On page 11.

18 A. Okay. All right.

19 (Document reviewed by the witness.)

20 BY MR. HANKINSON:

21 Q. The documents that are collected in
22 Exhibit 214 are from the year -- excuse me.

1 The document -- no. There are -- are
2 there multiple documents in Exhibit 214?

3 For instance, the first three pages seem
4 to be one. The next page -- two pages seem to be
5 another. And then the following page seems to be
6 separate. And I'm not sure if the last two pages
7 are part of that or not.

8 (Document reviewed by the witness.)

9 BY MR. HANKINSON:

10 Q. I'm sorry. Am I missing something?

11 I asked you if there were multiple
12 documents --

13 A. Oh. I thought -- I didn't know --

14 Q. -- in Exhibit 214.

15 A. -- that you were asking me.

16 Sorry.

17 Yeah, there appears to be multiple
18 documents in here.

19 I didn't realize you were asking me. I
20 thought you were --

21 Q. No problem.

22 The first document in Exhibit 214 dates

1 from 2010 --

2 A. Yep.

3 Q. -- as dated on the third page; is that
4 correct?

5 A. That's correct.

6 Q. The second document in Exhibit 214 is
7 dated April 9th, 2012; is that right?

8 A. That's correct.

9 Q. And there's a copyright date of -- never
10 mind.

11 The next three pages -- how many documents
12 are the next three pages? One or two?

13 A. Okay. You have the data sheet, and then
14 you have the --

15 DEPOSITION OFFICER: I couldn't hear you.

16 I can hear, "You have the data sheet, and
17 then you have the..."?

18 THE WITNESS: Sorry. I'm kind of mumbling
19 because I'm talking to myself here as I'm counting.

20 DEPOSITION OFFICER: Exactly. I need to
21 hear you.

22 THE WITNESS: So you have the data sheet,

1 which is the first three pages.

2 And then you have the FGED Society
3 document, which is two pages.

4 BY MR. HANKINSON:

5 Q. And that's from 2012?

6 A. Yes.

7 And then there is a document that is an
8 Illumina -- it says that "Illumina appreciates the
9 importance of MIAME," which is another document.

10 And then there is a document that
11 describes a Universal array, and that's two pages, I
12 think. Yes, that's right.

13 Q. The one-page that starts "As a microarray
14 manufacturer..." --

15 A. Yes.

16 Q. -- what is the date of that document, if
17 you know?

18 A. I don't know.

19 Q. The next two pages, the final two pages of
20 Exhibit 214, what is the date of that document --

21 A. I don't --

22 Q. -- if you know?

1 A. I don't know.

2 Q. Can I buy a unique 23-bp single-stranded
3 DNA oligo from Illumina?

4 A. Not today.

5 Q. Was there a time at which I could buy
6 that?

7 A. No. There was a time at which you could
8 buy oligos from us. So what I don't remember is
9 what the minimum length of the oligo was.

10 Q. Was there a time at which I could buy a
11 unique 23-bp single-stranded DNA oligo from Illumina
12 for use in BeadArray technology?

13 A. If you're referring to IllumiCodes, they
14 were an integral part of our array technology.

15 Q. They were not sold separately, so to
16 speak?

17 A. They were not sold separately. That's
18 correct.

19 Q. I'd like now to refer to paragraph 41 of
20 your declaration, and hand you what's being marked
21 as Exhibit 215.

22 (Whereupon, Possemato Exhibit Number

1 215 was marked for identification by
2 the Deposition Officer and is
3 attached hereto.)

4 BY MR. HANKINSON:

5 Q. Does Exhibit 215 have multiple documents
6 in it?

7 (Document reviewed by the witness.)

8 THE WITNESS: Yes.

9 BY MR. HANKINSON:

10 Q. Are all of the documents in Exhibit 215
11 dated from 2011?

12 (Document reviewed by the witness.)

13 THE WITNESS: No.

14 BY MR. HANKINSON:

15 Q. Please point me to each exception.

16 A. Okay. So -- I'm sorry -- but three pages
17 from the back of the document.

18 MR. HORNE: You can use production numbers
19 on the bottom if they exist.

20 THE WITNESS: Yeah. And this page -- so
21 it's the third-to-the-last page, and it has a
22 screenshot of Illuminotes Today, and it's dated

1 April of 2014.

2 And then the subsequent screenshot
3 following that is -- it looks like the inaugural
4 Illuminotes in April of 2006.

5 And then the last page is just a
6 continuation of that, it appears. Yep.

7 BY MR. HANKINSON:

8 Q. Do you see, prior to those documents,
9 within Exhibit 215, that each page has a little
10 prefix -- a number at the bottom ILLUM-086-, and
11 then a different number, and then it goes into the
12 -70s?

13 A. Yes, I do see that.

14 Q. The last three pages that you just
15 referred to do not have such a number; is that
16 correct?

17 A. That's correct.

18 Q. Do you see black boxes near "From,"
19 "Message," and "To" on the second-to-the-last page
20 of Exhibit 215?

21 A. I do see black boxes, yes.

22 Q. Is it your understanding that information

1 in the original of these two pages has been blocked
2 by the black boxes so that we can no longer see it?

3 A. Well, what appears to be on here is just
4 that the e-mail address has been blocked -- has been
5 blacked out.

6 Q. The "From," the "To," and something else
7 next to "Message"; is that right?

8 A. Yeah, I don't know what that is or what
9 that would be, but that's right.

10 Q. Do you know who this was sent from and
11 to?

12 A. From my recollection --

13 MR. HORNE: Vague.

14 Sorry.

15 THE WITNESS: Sorry.

16 From my recollection, it was sent from an
17 e-mail box that we had created that was Illumina
18 Community, and it was sent to our distribution list
19 of customers at the time, because this newsletter
20 was for customers who were using our products.

21 BY MR. HANKINSON:

22 Q. Oh. This wasn't a subscription service?

1 A. Well, it was a subscription service, but
2 with a subset of just customers.

3 Q. I mean, they didn't pay to receive this --

4 A. Oh, no.

5 Q. -- like a --

6 A. No.

7 Q. -- circulated newspaper?

8 A. No.

9 (Whereupon, Possemato Exhibit Number
10 202 was marked for identification by
11 the Deposition Officer and is
12 attached hereto.)

13 (Document reviewed by the witness.)

14 BY MR. HANKINSON:

15 Q. I'd like to refer to you to what is marked
16 as Exhibit 202. Could you please look at the page
17 that is marked ILLUM-0841.

18 A. Yes.

19 (Document reviewed by the witness.)

20 THE WITNESS: Okay.

21 BY MR. HANKINSON:

22 Q. Do you know what that is?

1 A. That's a genome analyzer.

2 Q. Do you know what date that was sold?

3 A. It began to be sold in 2007, but there
4 were -- as I mentioned earlier, there were several
5 iterations of the genome analyzer.

6 Q. You don't know which one this is?

7 A. These were skinned similarly, so it's
8 difficult to tell; this picture is not very clear.

9 Q. Can you please refer to the page that ends
10 -845?

11 I'm sorry. First go to page -843.

12 A. -843. Okay.

13 Q. What is the date of what I'm seeing on
14 page -843?

15 A. I do not know the date, but it
16 approximately would have been pre -- like at least
17 before 2005, 2006.

18 Q. Could you refer, please, to paragraph 11
19 of your Declaration, Exhibit B.

20 A. Okay.

21 Q. The second-to-last sentence is:

22 "All of Illumina's products

1 and services are branded with the
2 Illumina mark."

3 Do you see that?

4 A. Yes, I see that.

5 Q. What is your basis for saying that?

6 A. The basis is because Illumina is a master
7 brand, and the branding strategy. The logo appears
8 on all the products, and the Illumina name is in the
9 first part of all the formal product names.

10 So it's a monolithic branding strategy.

11 Q. Illumina partners with many other
12 businesses; is that correct?

13 A. Yes.

14 Q. And it also has acquired many businesses
15 over the years?

16 A. We've acquired some companies, yes.

17 Q. Those partners and acquired companies,
18 prior to becoming partners and acquired companies,
19 have had products that they sell or services that
20 they sell; is that correct?

21 A. Not all partners.

22 Q. But many have?

1 A. Many -- some partners, yeah, have sold
2 products and services.

3 Q. Are there transitional periods after the
4 partnership or after the acquisition in terms of
5 branding?

6 A. Absolutely.

7 MR. HORNE: Vague -- last question's
8 vague.

9 Sorry.

10 BY MR. HANKINSON:

11 Q. Why did you choose -- could you look at
12 paragraph 42 of your declaration.

13 A. Yes.

14 Q. Why did you choose to attach "Illumina
15 Publicly Reported Annual Financial Results" for the
16 years 2003 through 2013 to your declaration?

17 A. It's indicative of the growth of the brand
18 and the company's footprint.

19 Q. The company becoming larger?

20 A. And -- and be successful, yeah, and
21 growing.

22 (Brief pause in proceedings.)

1 MR. HANKINSON: I probably should have
2 asked this two minutes ago.

3 Could we take a break?

4 MR. HORNE: Yes.

5 MR. HANKINSON: Thanks.

6 DEPOSITION OFFICER: Off the record.

7 (Whereupon, a recess was held
8 from 4:58 p.m. to 5:16 p.m.)

9 DEPOSITION OFFICER: Back on the record.

10 MR. HORNE: I don't know what the
11 protective order says about confidentiality and how
12 long things remain confidential, but I want a chance
13 to look.

14 We didn't designate Naomi's.

15 And I don't think this whole thing, if any
16 of it, would be trade secret, but I want to have a
17 chance to review it before you go showing it to
18 clients.

19 So to the extent the protective order
20 doesn't have an automatic safe period, so to speak,
21 we want to maintain the highest level of designation
22 for the two until we get a chance to review the

1 transcripts.

2 MR. HANKINSON: How long do you want?

3 MR. HORNE: I don't know. It depends --
4 after we get the thing, a week or two after we get
5 it.

6 If for some reason you feel you need to
7 show it to the client or something to prepare your
8 stuff, we can talk. But I just wanted to --

9 MR. HANKINSON: Yeah, that's my only
10 question. We have a deadline at some point.

11 DEPOSITION OFFICER: Do you want this on
12 the record?

13 MR. HORNE: Let's go off the record.

14 MR. HANKINSON: Off the record.

15 DEPOSITION OFFICER: Off the record.

16 (Whereupon, at the hour of
17 5:20 p.m., the proceedings
18 were concluded.)
19
20
21
22

1 STATE OF CALIFORNIA)

2) .SS

3 COUNTY OF SAN DIEGO)

4 DEPOSITION OFFICER'S CERTIFICATE

I, Tracy M. Fox, hereby certify:

5 I am a duly qualified Certified Shorthand
6 Reporter in the State of California, holder of
Certificate Number 10449, issued by the Court
7 Reporters Board of California and which is in full
8 force and effect. (Bus. & Prof. S 8016)

9 I am not financially interested in this
10 action and am not a relative or employee of any
11 attorney of the parties, or of any of the parties.
12 (Civ. Proc. S 2025.320(a))

13 I am authorized to administer oaths or
14 affirmations pursuant to California Code of Civil
15 procedure, Section 2093(b) and prior to being
16 examined, the witness was first duly sworn by me.
17 (Civ. Proc. S 2025.320, 2025.540(a))

18 I am the deposition officer that
19 stenographically recorded the testimony in the
20 foregoing deposition and the foregoing transcript is
21 a true record of the testimony given.
22 (Civ. Proc. S 2025.540(a))

1 I have not, and shall not, offer or
2 provide any services or products to any party's attorney
3 or third party who is financing all or part of the
4 action without first offering same to all parties or
5 their attorneys attending the deposition and making
6 same available at the same time to all parties or
7 their attorneys. (Civ. Proc. S 2025.320(b))

8 I shall not provide any service or product
9 consisting of the deposition officer's notations or
10 comments regarding the demeanor of any witness,
11 attorney, or party present at the deposition to any
12 party or any party's attorney or third party who is
13 financing all or part of the action, nor shall I
14 collect any personal identifying information about
15 the witness as a service or product to be provided
16 to any party or third party who is financing all or
17 part of the action. (Civ. Proc. S 2025.320(c))

18 DATED: This day 18th of December, 2014.

19

20

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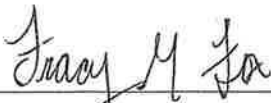
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TRACY M. FOX, C.S.R. 10449

Certified Shorthand Reporter

1 Karen Possemato c/o

2 KNOBBE MARTENS

3 10100 Santa Monica Boulevard, 16th Floor

4 Los Angeles, California 90067

5

6 Case: Illumina, Inc. v. Meridian Bioscience, Inc.

7 Date of deposition: December 4, 2014

8 Deponent: Karen Possemato

9

10 Please be advised that the transcript in the above

11 referenced matter is now complete and ready for signature.

12 The deponent may come to this office to sign the transcript,

13 a copy may be purchased for the witness to review and sign,

14 or the deponent and/or counsel may waive the option of

15 signing. Please advise us of the option selected.

16 Please forward the errata sheet and the original signed

signature page to counsel noticing the deposition, noting the

17 applicable time period allowed for such by the governing

18 Rules of Procedure. If you have any questions, please do

not hesitate to call our office at (202)-232-0646.

19

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4
Case: Illumina, Inc. v. Meridian Bioscience, Inc.
5 Witness Name: Karen Possemato
Deposition Date: December 4, 2014

6
7 I do hereby acknowledge that I have read
and examined the foregoing pages
8 of the transcript of my deposition and that:

9
10 (Check appropriate box):
() The same is a true, correct and
11 complete transcription of the answers given by
me to the questions therein recorded.
12 () Except for the changes noted in the
attached Errata Sheet, the same is a true,
13 correct and complete transcription of the
answers given by me to the questions therein
14 recorded.

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17 DATE WITNESS SIGNATURE

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ERRATA SHEET

7 Case: Illumina, Inc. v. Meridian Bioscience, Inc.
Witness Name: Karen Possemato
8 Deposition Date: December 4, 2014

Page No. Line No. Change

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Signature

Date

1 I have not, and shall not, offer or
2 provide any services or products to any party's attorney
3 or third party who is financing all or part of the
4 action without first offering same to all parties or
5 their attorneys attending the deposition and making
6 same available at the same time to all parties or
7 their attorneys. (Civ. Proc. S 2025.320(b))

8 I shall not provide any service or product
9 consisting of the deposition officer's notations or
10 comments regarding the demeanor of any witness,
11 attorney, or party present at the deposition to any
12 party or any party's attorney or third party who is
13 financing all or part of the action, nor shall I
14 collect any personal identifying information about
15 the witness as a service or product to be provided
16 to any party or third party who is financing all or
17 part of the action. (Civ. Proc. S 2025.320(c))

18 DATED: This day 18th of December, 2014.

19

20

21

22

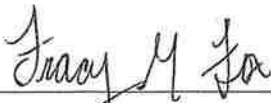
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TRACY M. FOX, C.S.R. 10449

Certified Shorthand Reporter

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

Illumina, Inc.,)	Opposition No.: 91194218.
)	
Opposer,)	
)	
v.)	
)	
Meridian Bioscience, Inc.,)	
)	
Applicant.)	
)	

DECLARATION OF KAREN POSSEMATO

I, Karen Possemato, declare as follows:

1. I have personal knowledge of the matters set forth herein and if called upon to testify, I could and would competently testify thereto.

2. I have been employed with Illumina, Inc. ("Illumina") since April 2004. In my current role as Chief of Staff I am responsible for communications, operations, and projects for the offices of the CEO and the President. In my previous role as Senior Director, Corporate Marketing, I was responsible for building Illumina's marketing organization and developing the strategic and tactical marketing of the company. I am familiar with the history of Illumina, including the development and marketing of its products and services. I am also familiar with Illumina's use of the marks ILLUMINA®, ILLUMINADX®, ILLUMINOTES™, and ILLUMICODE™.

3. Illumina is a global company that develops, manufactures, and markets genetic analysis tools and integrated systems for the analysis of genetic variation and function, and provides services related to the same. More specifically, Illumina develops and sells innovative array- and sequencing-based solutions for DNA and RNA analysis that serve as tools for



disease research and diagnosis, drug development, and for the development of molecular tests in the clinic. Illumina products and services serve life-sciences research, applied markets, and the molecular diagnostics market (which is part of the clinical diagnostic market). True and correct copies of Illumina marketing brochures and pages from Illumina's website <<www.illumina.com>> expounding on Illumina's commercial activities are attached hereto as Exhibit 201.

4. DNA sequencing is the process of determining the precise order of nucleotides, which are organic molecules that serve as subunits within a DNA molecule. DNA sequencing generally includes any method or technology that is used to determine the order of nucleotides in a strand of DNA.

5. By contrast, genotyping generally includes determining differences in the genetic make-up (genotype) of an individual or substance by examining specific portions of a DNA sequence and comparing that portion to a reference sequence.

6. Genotyping is often performed using "array" technology. Array technology generally refers to a collection of microscopic regions of DNA attached to a solid surface. Each region contains a specific DNA sequence, known as a probe. An array is used to determine whether a DNA sample contains the precise DNA sequence that corresponds to the probe on the region. For example, a sample from a human would be treated and then placed on the array. The array is then placed into a certain type of machine called a reader, which can determine whether a certain type of DNA sequence is present in the sample. This can indicate, for example, the presence of a disease, such as an infectious disease.

7. Since its founding, Illumina has extensively used ILLUMINA® as a house and product mark for its products and services. Illumina was founded in 1998 based on array technology.

8. Illumina first offered its array technology as part of its FastTrack™ services, through which customers would send a sample that Illumina would genotype at its own lab using

its array technology.

9. In 2002, Illumina began offering the applications that were previously available through its FastTrack™ services as the Illumina® BeadLab™. Essentially, Illumina would install a lab at its customers institutions based on the lab footprint of Illumina's own FastTrack™ services lab. The Illumina® BeadLab™ was customizable to meet each customer's specific needs, and included a number of readers, such as Illumina's BeadArray™ Reader, among other components used in the FastTrack™ services lab. By installing the Illumina® BeadLab™ at its customer's institutions, Illumina's customers were able to perform the same type of genotyping services offered through Illumina's FastTrack™ services.

10. Illumina's next product, the Illumina® BeadStation™, was also sold under the ILLUMINA® mark beginning in 2005. The BeadStation™ was a small-scale version of the Illumina® BeadLab™, being offered at a fraction of the cost—several hundred thousand dollars versus millions. The BeadStation™ included one BeadArray™ reader and was used by customers who did not need the capability of running thousands of arrays at a time.

11. Illumina has since developed a comprehensive line of products that address the scale and throughput of genetic analysis required to achieve the goals of precision/personalized medicine. Currently, Illumina's product line includes market-leading solutions for targeted to whole-genome sequencing and array based analysis. Illumina's products and services serve a range of interconnected markets, including life sciences, oncology, reproductive health, forensics, agrigenomics, population sequencing, consumer genomics and public health and its products are used by a broad range of genomic research centers, academic institutions, government laboratories, hospitals clinical research organizations, clinical diagnostic labs, and clinical reference labs, as well as pharmaceutical, biotechnology and consumer companies. All of Illumina's products and services are branded with the ILLUMINA® mark. Representative examples of the use of the ILLUMINA® mark are attached hereto as Exhibit 202.

12. Although Illumina began as a research company, it always aimed to enter the

clinical diagnostics market. For example, although Illumina's first products were used for genotyping, a major focus of genomics is to be able to more effectively diagnose and treat patients.

13. Thus, in 2005, in order to expand its footprint in the molecular/clinical diagnostic market, Illumina acquired a company named CyVera Corp. That acquisition gave Illumina access to a certain type of array technology called VeraCode®. As is the case with all of Illumina's products, Illumina branded its VeraCode® product with its ILLUMINA® mark. Illumina planned to develop VeraCode® into a diagnostics product. VeraCode® was similar to Illumina's other array technology. But rather than regions of nucleic acid on a chip, VeraCode® can include nucleic acid on glass beads suspended in a solution in a vial. The beads would be put into Illumina's BeadXpress® reader, which would read them individually.

14. In 2005, after purchasing CyVera, Illumina hired Mickie Henshall as the Associate Director Product Marketing, Diagnostics. Illumina hired Ms. Henshall to work exclusively on the marketing and promotion of Illumina's diagnostic products and services.

15. In addition to acquiring CyVera, Illumina collaborated with other companies as early as 2006 to bring its array technology to the diagnostic market. For example, in 2006, Illumina entered into an agreement to work with deCODE Genetics, Inc., to develop and commercialize DNA-based diagnostics in several major disease areas. Prior to its collaboration with Illumina, deCODE had developed various biomarkers that show an association to disease outcomes such as Alzheimer's and various other inherited diseases. Illumina and deCODE used Illumina's array technology to develop diagnostic tests for variants in genes linked to heart attack, type-2 diabetes, and breast cancer. Illumina and deCODE publically announced this collaboration. Attached hereto as Exhibit 3 is a true and correct copy of a public article from genomeweb.com dated May 15, 2006, describing the collaboration

16. Illumina also collaborated with ReaMetrix, Inc. in 2006. The companies planned to co-develop molecular diagnostic panels for a range of disease areas, including diabetes and

cardiovascular disease. The companies agreed that Illumina would provide its VeraCode® technology, and ReaMetrix would develop, validate, and market diagnostic tests based upon Illumina's BeadXpress® diagnostic platform. Illumina and ReaMetrix publically announced this collaboration in July 2006. Attached hereto as Exhibit 203 is a true and correct copy of an Illumina press release dated July 20, 2006, regarding the collaboration.

17. In January 2008, Illumina created a Diagnostics Business Unit in order to expand its presence in the molecular diagnostics market (which is part of the clinical diagnostic market) and manage its diagnostics products. By this time, Illumina had also formed a regulatory and quality group to support its growth in the molecular diagnostics market.

18. In October 2009, Illumina filed two submissions for FDA clearance in connection with its BeadXpress® platform. The first submission was for in-vitro diagnostic use of the BeadXpress® System with cleared genotyping tests. Illumina's second submission was for its VeraCode® in-vitro diagnostic genotyping test for Factor V and Factor II. Patients with Factor V and Factor II mutations have an inherited blood clotting disorder known as thrombophilia, which increases the patient's risk for venous thrombosis. The FDA cleared both of Illumina's submissions in April 2010.

19. In January 2011, Illumina acquired Epicentre Biotechnologies Corporation. Epicentre manufactures specialty enzymes and biological preparations for use in molecular biology research and medical diagnostics. For example, Epicentre markets the QuickExtract™ Bacterial DNA Extraction Kit. This kit provides a simple method for extracting DNA for use with applications such as creation of lab-developed tests, and has been tested with a range of bacteria, including *Streptococcal* bacteria, *E. Coli*, and *Salmonella typhimurium*. Accordingly, this kit is useful across a number of fields, including in life-sciences research, applied markets, and the molecular diagnostics market. Attached hereto as Exhibit 204 is a true and correct copy of a QuickExtract™ Bacterial DNA Extraction Kit information sheet. Attached hereto as Exhibit 205 is a true and correct copy of an Illumina press release dated January 11, 2011, about this

acquisition and the products now manufactured by Illumina. Although the "EpiCentre" brand was kept as a child brand after the initial acquisition, Illumina soon began branding the QuickExtract™ Bacterial DNA Extraction Kit as "EpiCentre, an Illumina company."

20. In 2011, Illumina began a reorganization that created three business units—Diagnostics, Life Sciences, and Translational & Consumer Genomics ("TCG"). Illumina's Diagnostics unit was focused on FDA-cleared in-vitro diagnostic offerings.

21. In October 2013, Illumina announced its most-recent reorganization undertaken to maintain growth in its existing markets and to enable Illumina to move into new markets. For example, Illumina has reorganized into five business units, including a new Oncology business unit to serve the cancer diagnostics field.

22. Illumina also entered the diagnostics market with its DNA sequencing business.

23. In 2007, Illumina acquired Solexa, Inc., a company that had developed a new method for genome sequencing referred to as next generation sequencing ("NGS"). As sequencing technology has improved over the years, the cost of sequencing a human genome has decreased from \$3 billion to \$1,000. These advances have made sequencing technology more accessible, which in turn has increased the applications for sequencing, and in particular NGS technology, including for use in clinical diagnostics. Illumina has been credited with achieving many of the technological advances that reduced the cost of sequencing a human genome.

24. Indeed, many genome sequencing projects have shared the common goal of understanding how genetics influence human health. For example, beginning with the Human Genome Project, which was the first effort to sequence an entire human genome, a number of public projects have ensued to find the genetic underpinnings of human health. More specifically, the International HapMap Project began in 2002 with the goal of developing a haplotype map ("HapMap") of the human genome. The purpose of the map was to catalogue common genetic variations among humans to establish connections with diseases. The project

used Illumina arrays. In 2007, the National Human Genome Research Institute (NHGRI) began its ClinSeq project, which examined genome sequencing in clinical research. The project used Illumina sequencers. The International Cancer Genome Consortium, which was founded in 2008, aimed to generate a catalogue of genetic abnormalities in tumors which are of clinical importance. Illumina was selected as a preferred vendor in 2011. The 1000 Genomes Project began in 2008. This was an effort to sequence 1000 genomes to create a picture of human genetic variation with clinical utility. Illumina scientists were collaborators on the program.

25. Since the completion of the Human Genome Project in 2001, genetic sequencing has been moving into clinical diagnostic applications. One of the first goals was to enable more economic whole-genome sequencing so that whole-genome sequencing can realistically and practically be used for diagnostic applications. Illumina made this possible with the launch of its HiSeq® sequencer in 2010. Since then, Illumina has launched additional sequencing instruments that have further increased the utility of sequencing in clinical diagnostic applications. For example, Illumina launched its MiSeq® instrument in 2011, which is smaller and less expensive than Illumina's HiSeq®, and allows for more focused sequencing applications.

26. In November 2011, Illumina partnered with Siemens Healthcare Diagnostics to make Siemens' molecular HIV tests compatible with Illumina's MiSeq® platform and to develop additional sequencing-based infectious disease assays for the clinical diagnostics market. Attached hereto as Exhibit 17 is a true and correct copy of a news article dated November 2, 2011, announcing Illumina's partnership with Siemens. Illumina's MiSeq® bench-top sequencing system uses NGS technology for genome sequencing. Through its partnership with Siemens, Illumina sought to drive adoption of its NGS technology in the clinical diagnostics market.

27. Illumina also began offering diagnostic whole-genome sequencing on its HiSeq 2500 by September 2012. Illumina's diagnostic whole-genome sequencing services require a

physician's prescription and are performed in Illumina's CLIA-certified lab. "CLIA" refers to the Clinical Laboratory Improvement Amendments of 1988, which are federal regulatory standards for clinical laboratory testing. In the United States, any facility that performs laboratory testing on human-derived specimens for the purpose of providing information for diagnosis, prevention, or treatment of disease or impairment, or for health assessments must be CLIA-certified. Attached hereto as Exhibit 22 is a true and correct copy of a news article dated September 12, 2012 discussing Illumina's TruSight® products and diagnostic whole-genome sequencing services.

28. During the 2012-13 timeframe, Illumina was looking to acquire companies to expand its presence in the diagnostic space.

29. In January 2013, Illumina further expanded its push into the diagnostics business through its acquisition of Verinata Health. Attached hereto as Exhibit 25 is a true and correct copy of a news article dated January 7, 2013, discussing this acquisition.

30. Verinata's verifi® test is a non-invasive prenatal test that is used to diagnose genetic diseases, such as Down syndrome. The verifi® test uses DNA sequencing to analyze fragments of fetal DNA that can be found in a pregnant woman's blood, offering a non-invasive alternative to traditional invasive tests like amniocentesis, which carry a slight risk of inducing miscarriage. Indeed, such non-invasive tests are quickly becoming the standard of care, providing higher quality data with less risk than an amniocentesis. Attached hereto as Exhibit 206 is a true and correct copy of an Illumina press release dated November 1, 2013, announcing the availability of the verifi® test to pregnant women in California through California's Prenatal Screening Program.

31. Moreover, other non-invasive pre-natal testing companies are using Illumina sequencers to develop their own non-invasive prenatal diagnostic tests. For example, Illumina entered into an agreement with Natera, Inc., in September 2013 to supply Natera with Illumina's HiSeq® 2500 sequencing system for performing Natera's non-invasive prenatal test,

Panorama™. Attached hereto as Exhibit 207 is a true and correct copy of an Illumina press release dated September 4, 2013, announcing the agreement with Natera.

32. In July 2013, HistoGenetics, the leader in high-resolution sequence-based human leukocyte antigen ("HLA") testing services, selected the MiSeq® system for use in its CLIA laboratory. HistoGenetics will use Illumina's MiSeq® system to sequence HLA genes, variations of which have known associations with a wide variety of autoimmune diseases, infectious diseases, and some cancers. Attached hereto as Exhibit 208 is a true and correct copy of an Illumina press release dated July 22, 2013, announcing HistoGenetics' selection of Illumina's MiSeq® system.

33. By July 2013, Illumina applied the CE mark to its MiSeqDx® Cystic Fibrosis System, and was finalizing plans to commercialize this system in a number of European countries. CE marks are a mandatory conformity marking for certain products, including in-vitro diagnostic medical devices, sold within the European Economic Area. Illumina's MiSeqDx® Cystic Fibrosis System was developed for the clinical molecular diagnostics market and leverages Illumina's NGS technology to provide rapid and accurate identification of variants in the cystic fibrosis transmembrane conductance regulator ("CFTR") gene. By sequencing the entire CFTR gene, the MiSeqDx® Cystic Fibrosis System shortens the time for clinical diagnosis of cystic fibrosis, a life-threatening, inherited disorder. Attached hereto as Exhibit 209 is a true and correct copy of an Illumina press release dated July 1, 2013, announcing Illumina's application of the CE mark to its MiSeqDx® Cystic Fibrosis System.

34. In September 2013, Illumina applied the CE mark to an expanded use of the MiSeqDx® System in clinical diagnostic laboratories, allowing these laboratories to develop diagnostic tests using Illumina's MiSeqDx® Universal Kit on the MiSeqDx®. Such use greatly expands the opportunity for clinical diagnostic laboratories to offer diagnostic tests for wide-ranging applications including genetic and infectious diseases and cancer. Attached hereto as Exhibit 210 is a true and correct copy of an Illumina press release dated September 25, 2013,

announcing Illumina's application of the CE mark to expanded use of the MiSeqDx® System.

35. The reagents used with the CE-marked MiSeqDx Systems discussed in the previous two paragraphs were manufactured in the United States and sent to Europe bearing the ILLUMINA mark.

36. In November 2013, Illumina received FDA clearance to sell its MiSeqDx® sequencers for open-use, which allows Illumina to promote the MiSeqDx® to clinical diagnostic laboratories for the development of their clinical diagnostic tests. The FDA also cleared two tests for cystic fibrosis to be performed on the MiSeqDx®. Attached hereto as Exhibit 34 is a true and correct copy of a news article dated November 26, 2013, discussing the FDA clearance of Illumina's MiSeqDx® platform and cystic fibrosis tests.

37. As stated above, FDA-clearance as an open-use platform allows Illumina customers to use the MiSeqDx® to develop their own clinical diagnostic tests. As one example, in January 2014 Illumina entered into a multi-year agreement with Quest Diagnostics, one of the largest clinical diagnostic labs in the United States. That agreement gave Quest rights to use Illumina's sequencing and array technology to develop and commercialize its own diagnostic tests. Attached hereto as Exhibit 211 is a true and correct copy of an Illumina press release dated January 9, 2014, announcing the agreement with Quest.

38. In January 2014, Illumina announced its plan to submit an in-vitro diagnostic version of the HiSeq® 2500 system for FDA premarket clearance by the end of 2014. Attached hereto as Exhibit 212 is a true and correct copy of an Illumina press release dated January 16, 2014, discussing Illumina's plan for market expansion.

39. Illumina also intends to develop tests with its other partners to bring NGS to clinical diagnostics. For example, Illumina has partnered with Amgen, Inc., to develop a test for companion diagnostics for Amgen's colon cancer drug. Through this partnership, Illumina and Amgen hope to develop a test used to identify candidates for treatment with Amgen's Vectibix® for metastatic colorectal cancer. Attached hereto as Exhibit 213 is a true and correct copy of an

Illumina press release dated January 15, 2014, announcing the agreement with Amgen. In June 2014, Illumina also entered into a multi-year supply agreement with LabCorp, another of the largest clinical diagnostic labs in the United States. The agreement allows LabCorp to purchase a broad range of Illumina products for the development of diagnostic tools in multiple specialties such as genetic testing, oncology, transplant medicine, and forensics.

40. Since at least as early as August 2002, Illumina has used and continues to use the mark ILLUMICODE™ in connection with DNA microarrays. Representative examples of the use of the ILLUMICODE™ mark are attached hereto as Exhibit 214.

41. Since at least as early as April 2006, Illumina has used and continues to use the mark ILLUMINOTES™ in connection with newsletters featuring information in the fields of nucleic acid sequencing and genotyping, medical diagnostics, medical research, life sciences, biology, molecular pathology, molecular diagnostics, laboratory medicine, biotechnology, and genetics. Representative examples of the use of the ILLUMINOTES™ mark are attached hereto as Exhibit 215.

42. Illumina is a publicly traded company (NASDAQ) with a current market capitalization of just over \$25 billion. Attached hereto as Exhibit 216 is a true and correct copy of an excerpt of Illumina's publicly reported annual financial results for 2003 showing Illumina's statement of operations data. Attached hereto as Exhibit 217 is a true and correct copy of an excerpt of Illumina's publicly reported annual financial results for 2004 showing Illumina's statement of operations data. Attached hereto as Exhibit 218 is a true and correct copy of an excerpt of Illumina's publicly reported annual financial results for 2005 showing Illumina's statement of operations data. Attached hereto as Exhibit 219 is a true and correct copy of an excerpt of Illumina's publicly reported annual financial results for 2006 showing Illumina's statement of operations data. Attached hereto as Exhibit 220 is a true and correct copy of an excerpt of Illumina's publicly reported annual financial results for 2007 showing Illumina's statement of operations data. Attached hereto as Exhibit 221 is a true and correct copy of an

excerpt of Illumina's publicly reported annual financial results for 2008 showing Illumina's statement of operations data. Attached hereto as Exhibit 222 is a true and correct copy of an excerpt of Illumina's publicly reported annual financial results for 2009 showing Illumina's statement of operations data. Attached hereto as Exhibit 223 is a true and correct copy of an excerpt of Illumina's publicly reported annual financial results for 2010 showing Illumina's statement of operations data. Attached hereto as Exhibit 224 is a true and correct copy of an excerpt of Illumina's publicly reported annual financial results for 2011 showing Illumina's statement of operations data. Attached hereto as Exhibit 225 is a true and correct copy of an excerpt of Illumina's publicly reported annual financial results for 2012 showing Illumina's statement of operations data. Attached hereto as Exhibit 226 is a true and correct copy of an excerpt of Illumina's publicly report financial results for the quarterly period ending March 21, 2013. Attached hereto as Exhibit 227 is a true and correct copy of an excerpt of Illumina's publicly report financial results for the quarterly period ending June 30, 2013. Attached hereto as Exhibit 228 is a true and correct copy of an excerpt of Illumina's publicly report financial results for the quarterly period ending September 29, 2013.

43. Illumina is a well-known technology company and has frequently been noted to be an industry leader. True and correct copies of articles discussing Illumina are attached hereto as Exhibit 229.

44. Illumina has a significant budget for marketing and selling its products and services. During the period of January 2008 through December 31, 2013, Illumina has spent over \$8 million in advertising production cost, space and fees, over \$6.8 million in direct marketing and electronic marketing and over \$4.2 million in public relations including news releases and agency fees. These expenditures represent just a portion of Illumina's total marketing expenses during the noted period. Approximately 20% of these marketing expenses were targeted to clinical diagnostic customers.

45. I am familiar with Genomeweb and Bio-IT World, which are publications cited in

Illumina's declarations and notice of reliance.

46. Genomeweb is an online publisher that, according to its website <http://www.genomeweb.com/about>, serves "the global community of scientists, technology professionals, and executives who use and develop tools in molecular biology research and molecular diagnostics." This online resource and series of e-newsletters is focused on the science of genomics and the application of genomic technology in a variety of markets, as well as the business news in the field. Genomeweb's newsletter areas of focus are reflective of this. (See <http://www.genomeweb.com/subscriptions>.) Genomeweb is used and read in both clinical and research environments as Genomeweb is a great "central source" to track the genomics industry and its impacts. In March 2011, Genomeweb launched Clinical Sequencing News due to increasing demand for coverage of the rapid migration of genomics into the clinical space.

47. I recently ran a key word search for "illumigene" on Genomeweb's website. The search returned a number of articles about Meridian and its Illumigene products. The search also asked "Did you mean: Illumina". Exhibit 230 attached hereto is a true and correct copy of the results of my search.

48. Bio-IT World's Weekly Update newsletter and News Bulletins, according to its website http://www.bio-itworld.com/bioit_Content.aspx?id=137901, "cover the application of informatics, IT and computer science in biomedical research and drug discovery." Because genomics generates patient data (genomic data) that needs to be integrated with other electronic data in health management, NGS, consumer genomics, personalized medicine, and patient stratification are all topics of interest. Bio-IT World also holds events covering various topics across the research health-care spectrum. (See http://www.bio-itworld.com/Featured_Events.aspx.) Illumina has advertised in this publication in the past to reach clinicians, hospital Chief Information Officers, and other clinical audiences, as well as research customers interested in IT-related genomic challenges.

49. I have also reviewed the website of another publication, Clinica. According to its

website <http://www.clinica.co.uk/aboutus/>, Clinica is a "leading source of regulatory, market and competitor information for the medical devices and diagnostics industries. The main product sectors covered by Clinica include cardiovascular, IVDs, orthopaedics, surgical & wound care, cellular & genetic and neurological."

50. I have also reviewed the website of another publication, IVD Technology, which is now called Medical Device And Diagnostic Industry (MD+DI). IVD Technology is, according to its website <http://www.mddionline.com/about>, "an online and print resource exclusively for original equipment manufacturers of medical devices and in vitro diagnostic products."

The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements and the like may jeopardize the validity of the application or document or any registration resulting therefrom, declares that all statements made of his/her own knowledge are true; and all statements made on information and belief are believed to be true.

Executed this 7th day of November 2014 at San Diego, California


Karen Possemato

19284189

CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing OPPOSER'S DECLARATION OF KAREN POSSEMATO upon Applicant's counsel by depositing one copy thereof in the United States Mail, first-class postage prepaid, on November 7, 2014, addressed as follows:

J. Michael Hurst
Keating Muething & Klekamp PLL
One East 4th Street
Suite 1400
Cincinnati, OH 45202



Sarah Beno Couvillion

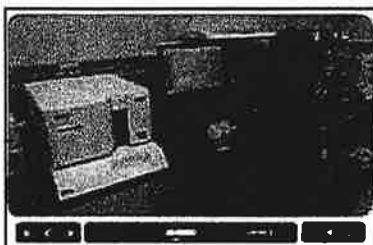
Exhibit 54



1-54



Multiplex Detection of Bacteria in Complex Clinical and Environmental Samples using Oligonucleotide-coupled Fluorescent Microspheres



Multiplexed Fluorometric ImmunoAssay Testing Methodology & Troubleshooting Videos courtesy of Journal of Visualized Experiments (JoVE).

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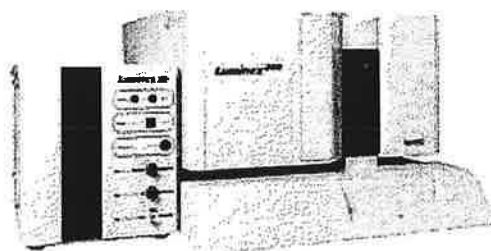
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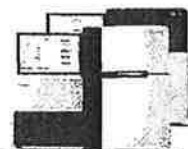
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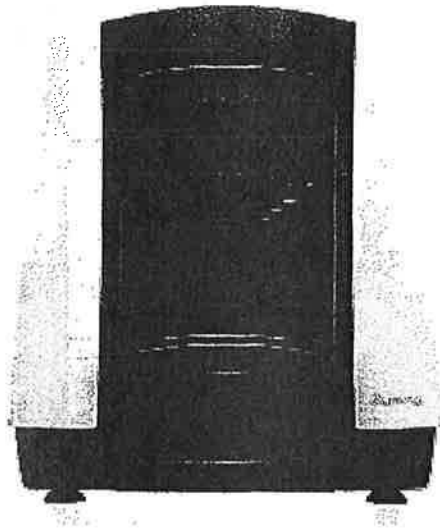
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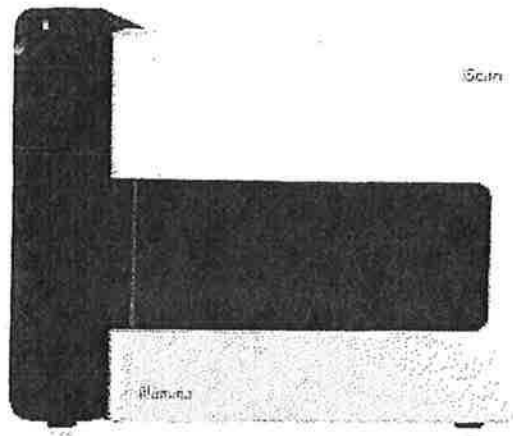
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Whole-Genome Genotyping and Copy Number Variation Analysis

Since they were first developed in 2005, whole-genome genotyping (WGGT) arrays have become an important tool for discovering variants that contribute to human diseases and phenotypes. The two primary applications of this technology, genome-wide association studies (GWAS) and copy number variant (CNV) analysis, have helped researchers begin to unravel the complex genetic architecture behind diseases such as diabetes and Crohn's disease, and traits such as hair and eye color.

Illumina's WGGT Infinium BeadChips offer researchers the flexibility to genotype samples with hundreds of thousands to millions of markers that deliver dense genome-wide coverage with the most up-to-date content available from the scientific community. Markers on the BeadChips are strategically selected by Illumina scientists to provide maximum coverage of the genome for both association testing and copy number detection.

The Omni Family of Microarrays

The latest generation of Infinium WGGT products is The Omni Family of Microarrays. This flexible, complimentary family of microarrays represents a revolution in array design, delivering up to 5 million makers per sample and offering an unprecedented amount of customizability. Designed from next-generation sequencing data from international projects such as the 1000 Genomes Project, Omni microarrays deliver unrivaled coverage of the genome. Access to whole-genome sequencing data provides the most complete picture of the extent of variation, allowing Illumina scientists to select the most informative markers to provide superior power to detect trait- and disease-associated variants.

More...

Custom Mid- to High-plex Genotyping

For researchers who want to study focused genomic regions of interest, or are interested in organisms for which there are no standard products, Illumina offers a broad range of custom genotyping options. Customized iSelect BeadChips can be easily developed to fit any experimental design, allowing customers to select the ideal solution for their loci multiplexing and sample throughput requirements. Convenient online tools and Illumina representatives are available to help you design and select your markers of interest, and choose the assay and customized products to best suit your research goals.

More...

Focused Genotyping

Focused genotyping supports a variety of applications such as candidate-gene studies in cancer, cardiovascular disease, and admixture mapping. Illumina also works closely with major animal consortia to develop genome-wide genotyping products for non-human organisms, including both animal and plant species.

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Cytogenetic Analysis

Structural variability is a substantial source of genetic variation that has a major influence on phenotypic variation. Cytogenetic analysis allows researchers to profile chromosomal aberrations such as amplifications, deletions, rearrangements, point mutations, copy number changes, and copy-neutral loss of heterozygosity (LOH) events.

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Linkage Analysis

Linkage analysis provides researchers a powerful method for mapping the location of disease-causing loci by identifying genetic markers that are co-inherited with a phenotype of interest. Illumina's linkage analysis BeadChips present the optimal solution for identifying regions of statistically unequivocal linkage by delivering the information content, call rates, and accuracy that enable discovery of links between familial genotype and phenotype in both monogenic and polygenic disorders.

More...

Array-Based Methylation Analysis

DNA methylation plays a critical role in the regulation of gene expression and has been implicated in the etiology of many human diseases including cancer. Methylation profiling with BeadArray technology allows researchers to analyze the effects of aberrant methylation (either hyper- or hypomethylation) for a variety of applications. Illumina has developed a robust methylation profiling platform that provides quantitative methylation measurement at the single-CpG-site level, providing the highest resolution for understanding epigenetic changes.

More...

Transcriptome Analysis

RNA sequencing has revolutionized the exploration of gene expression. Advances in the sequencing workflow, from sample preparation through data analysis, enable rapid profiling and deep investigation of the transcriptome. With RNA sequencing, you can characterize all transcriptional activity, coding and non-coding, in any organism without a priori assumptions.

Illumina's unique combination of long and short reads, single and paired-end sequencing, strand specificity, and capacity for tens of millions to billions of reads per run allows you to

- annotate coding SNPs
- discover transcript isoforms
- identify regulatory RNAs
- characterize splice junctions
- determine the relative abundance of transcripts

With the greatest daily output available for any sequencing system, transcript profiles can be generated in a single day. RNA sequencing reads can be aligned across splice junctions to identify isoforms, novel transcripts and gene fusions. Identify and quantify both rare and common transcripts, with over six orders of magnitude of dynamic range. Reveal the hidden world of non-coding RNA architecture without prior information.

More...

FFPE Sample Analysis

Formalin-fixed, paraffin-embedded (FFPE) samples are preserved tissue samples that are generally associated with disease. Many of these samples represent clinical outcomes, which could provide a potential gold mine of information when linked with underlying expression profiles. FFPE samples generally contain partially degraded RNA, so transcription analysis is a challenge for many gene expression assays. By using unique PCR and labeling steps based on the proven GoldenGate chemistry, Illumina's DASL assays provide high-quality data from degraded RNA samples. The DASL assay is available in the Whole-Genome DASL Assay, a fixed content, whole-genome profiling panel.

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Innovative technologies

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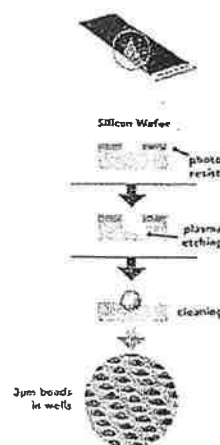
BeadArray Technology

A fundamentally different approach to high-density microarrays

Illumina's BeadArray Technology is based on 3-micron silica beads that self assemble in microwells on either of two substrates: fiber optic bundles or planar silica slides. When randomly assembled on one of these two substrates, the beads have a uniform spacing of ~5.7 microns. Each bead is covered with hundreds of thousands of copies of a specific oligonucleotide that act as the capture sequences in one of Illumina's assays. BeadArray technology is utilized in Illumina's iScan System for a broad range of DNA and RNA analysis applications. The original Infinium II Assay was great, but Infinium HD is remarkable. Most samples have an average call rate of 99.9% off the shelf, which makes downstream curation of data a whole lot easier. For those who aren't curating their data, there's much less downstream work because there is less likelihood of false positives and negatives due to the higher sample call rates. In addition to data quality, the ability to run four samples per chip clearly gets to the answers a lot faster.

BeadArray technology is deployed on either of two multi-sample array formats for DNA or RNA-analysis applications. With multi-sample BeadChip formats, uniform pits are etched into the surface of each substrate to a depth of approximately 3 microns prior to assembly. Beads are then randomly assembled and held in these microwells by Van der Waals forces and hydrostatic interactions with the walls of the well.

The Universal BeadChip format is used in Illumina's GoldenGate Genotyping and Focused Arrays applications. The BeadChip format is used in Illumina's Infinium Genotyping, DASL Gene Expression, and Focused Arrays applications.



Illumina multi-sample array formats

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Innovative technologies

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Omni Arrays

Dig deeper into your research. Make new discoveries. Tailor your studies.

The new Omni5 harnesses over ten years of genomic research, capturing variation down to 1% MAF. With more than 4.3 million high-value markers. And room for 500k of your own.

It's the most powerful genotyping array for your whole-genome studies yet. Take a closer look at the Omni5.

Omni Roadmap. Delivered.

Since the Omni family of microarrays was launched in 2009, we've offered an expanding selection of flexible arrays featuring only the most informative common and progressively rare variants. Delivering the most powerful markers selected from the International HapMap Project and the 1000 Genomes Project. Built with input from thought leaders in the human genetics research community. To ensure these markers would most effectively advance your studies.

Now the Omni5 is here. This flagship array dramatically expands the catalog of rare variants, offering unprecedented coverage of the genome, including high-value regions that deliver the most power to identify variants associated with disease.

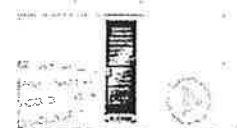
An array for any study. Any budget.

The Omni family gives you the flexibility to study the widest range of genetic variation—no matter your study size, sample population, research focus, or budget. Get the most comprehensive coverage of common and rare variants with the Omni5. Or, start smaller and build your variant collection with Omni products as your study grows.

Wherever you begin, you're guaranteed to be working with the most robust family of microarrays. All backed by the powerful Infinium Assay. With the highest-throughput. Intelligent tag-SNP selection. Cutting-edge content. All making the most of what this decade of genomic research has revealed. Giving you the power to effectively drive your next-gen GWAS studies—and discoveries.

[View the collection of Omni products.](#)

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Video | Infinium Assay
Driving Genomic Discovery

Discover the technology

» Watch the Infinium Arrays animation



Video | Next-Gen GWAS:
Illumina's Omni Roadmap

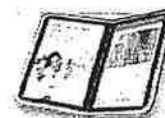
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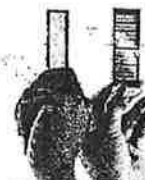


Launch the chip selector

» Select the best array for your research.



Read the e-book »
Read about the evolution of
Omni arrays.



**Explore hybrid workflow
options »**
Expand the power of your
study—next-gen sequencing
and arrays.

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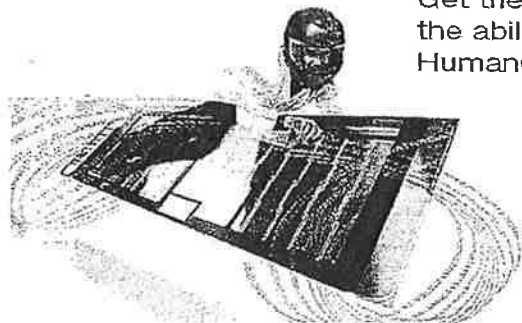

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Applications

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GWAS

GWAS has already proven very successful as an analytical approach to help researchers identify regions of the genome that harbor causative alleles for a trait or disease. This is accomplished by evaluating whole-genome genotypes across a large number of DNA samples and identifying those genetic variants that occur more frequently in people with a given trait or disease (cases), relative to those without the trait or disease (controls). Those variants that have statistically significant allele frequencies across the two groups of samples are said to be associated with that phenotype. Once an association is identified, it serves as an indicator to the region of the genome where causative variants are likely to exist. The use of GWAS to uncover these variants has proved immensely successful, identifying thousands of variants in hundreds of publications in a few short years. However, much remains to be discovered as researchers embark on a next-generation of GWAS, using new microarrays that allow detection of rarer variation and expand the catalog of diseases, traits, and populations studied.

Structural Variation Analysis

Structural Variation, is thought to be a significant contributor to the genetic basis of human disease. The same raw signal intensity data that is used to call genotypes can be used to identify regions where the genome contains either increased or decreased gene copy numbers. Furthermore, the added information of genotypes allows researchers to identify copy number neutral loss-of-heterozygosity. Dense marker spacing on the Omni microarrays, coupled with the sensitive Infinium assay and Illumina's high-precision array scanners, offer researchers a powerful solution for analyzing a range of structural variants.

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Genome-Wide Association Studies Product Roadmap - Illumina

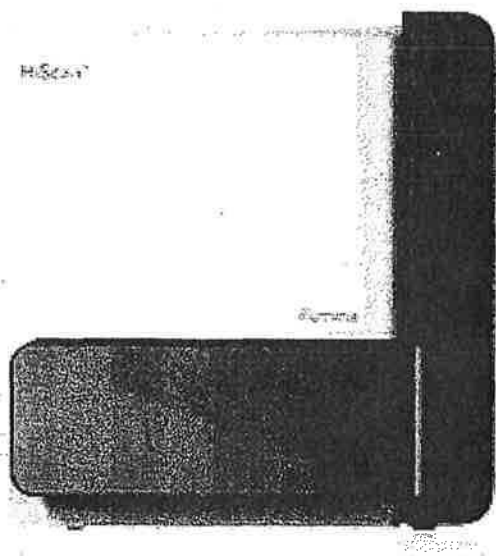
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Protein Analysis	Eco Real-Time PCR System	Illumina Connect	Assay Design Tool	Legal
Real-Time PCR	Software		Product Files	California
Agrigenomics	BaseSpace		Eco Real-Time PCR Support	Transparency in Supply Chain
Cytogenetics			Customer Service	
Cancer Genomics			Training	

Innovative technologies

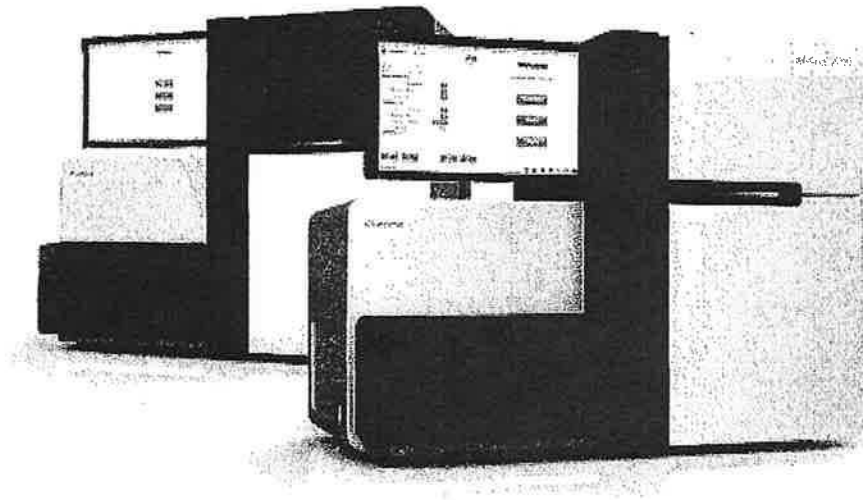
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Powerful array scanner,
expandable to add next-
gen sequencing

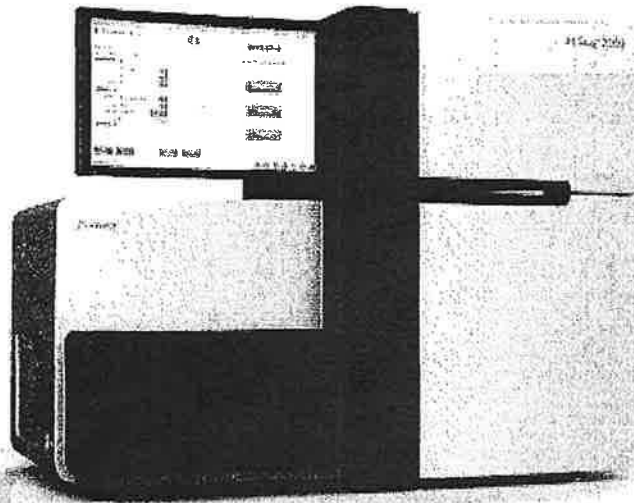


Genome today, interpreted tomorrow

The world's most powerful sequencer, now
with a rapid-run mode.

Coming mid-2012.

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Empowering your studies
like no other

Highest throughput.

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HiSeq™ Sequencing Systems

Redefining the trajectory of sequencing.

HiSeq System Highlights

- High Accuracy and Unprecedented Output:**
Generate up to 600 Gb per run with the highest yield of data greater than Q30.
- Breakthrough User Experience:**
Easily set up runs with simplified library prep, automated clonal amplification, pre-configured, plug-and-play reagents, simple flow cell loading, touch screen-enabled user interface, and integrated paired-end fluidics.
- Unmatched Cost-Effectiveness:**
Unrivalled output and ease of use with the industry's simplest sequencing workflow provide the lowest overall operating cost.
- Flexibility:**
HiSeq 1000 offers broader access to HiSeq technology, providing an easy upgrade path to the HiSeq 2000 as sequencing needs change.

Sequence at a Scale Never Before Possible

HiSeq Sequencing Systems combine Illumina's proven and widely-adopted, reversible terminator-based sequencing by synthesis (SBS) chemistry with innovative engineering. Comprised of the HiSeq 2000 (Figure 1) and HiSeq 1000 systems, this high-performance sequencing family combines human interaction design features and the easiest sequencing workflow, setting a new standard for simplicity and user experience.

The HiSeq 2000 sequencing system delivers the industry's highest sequencing output and fastest data generation rate. With the industry's simplest sequencing workflow and unmatched cost effectiveness, HiSeq 2000 has lowered the cost of whole-human genome sequencing to unrivaled levels.

Offering the same outstanding user experience and cost per data output (Gb), the HiSeq 1000 enables researchers to access HiSeq performance, with a built-in upgrade path should sequencing throughput needs change.

Unprecedented Output

HiSeq Systems make it possible for individual labs to take on the largest and most complex sequencing studies at a lower cost. With cutting-edge scanning and imaging technology, clusters on both surfaces of the flow cell can be sequenced, dramatically increasing the number of reads, sequence output, and data generation rate. The ultra-high output and speed of the two flow cell HiSeq 2000 makes it possible to sequence > 5 human genomes at ~30x coverage simultaneously, up to 192 gene expression samples or 100 exome samples in

a single run. The HiSeq 1000 System is an exceptionally powerful tool for researchers who do not require the throughput of a HiSeq 2000. It enables researchers to sequence > 2 human genomes at ~30x coverage or 96 gene expression samples in one run.

Breakthrough User Experience

Innovative design features make HiSeq Systems the easiest-to-use next-generation sequencing systems (Figure 2). Flow cells are loaded on the vacuum-controlled loading dock. Pre-configured, plug-and-play reagents sufficient for up to 200 cycles plus indexing, drop into racks in the machine's chiller compartment, requiring only two minutes of hands-on time. A simple touch screen user interface, including on-screen, step-by-step instructions with embedded multimedia help, simplifies run setup. Real-time progress indicators provide at-a-glance status, and remote monitoring allows a single user to check progress on multiple systems from any browser or internet-enabled phone.

HiSeq 2000 can be operated in single or dual flow cell mode, offering unmatched experimental flexibility and instrument scalability. Its independently-operable flow cells allow applications requiring different read lengths to run simultaneously. The single flow cell HiSeq 1000 delivers the same user experience and output per flow cell, and can be easily upgraded to the dual flow cell HiSeq 2000 to meet growing research needs.

Figure 1: HiSeq 2000 System

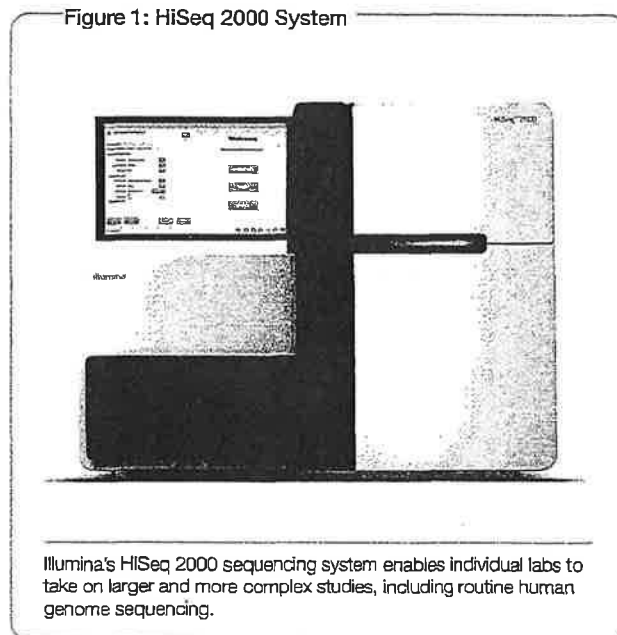
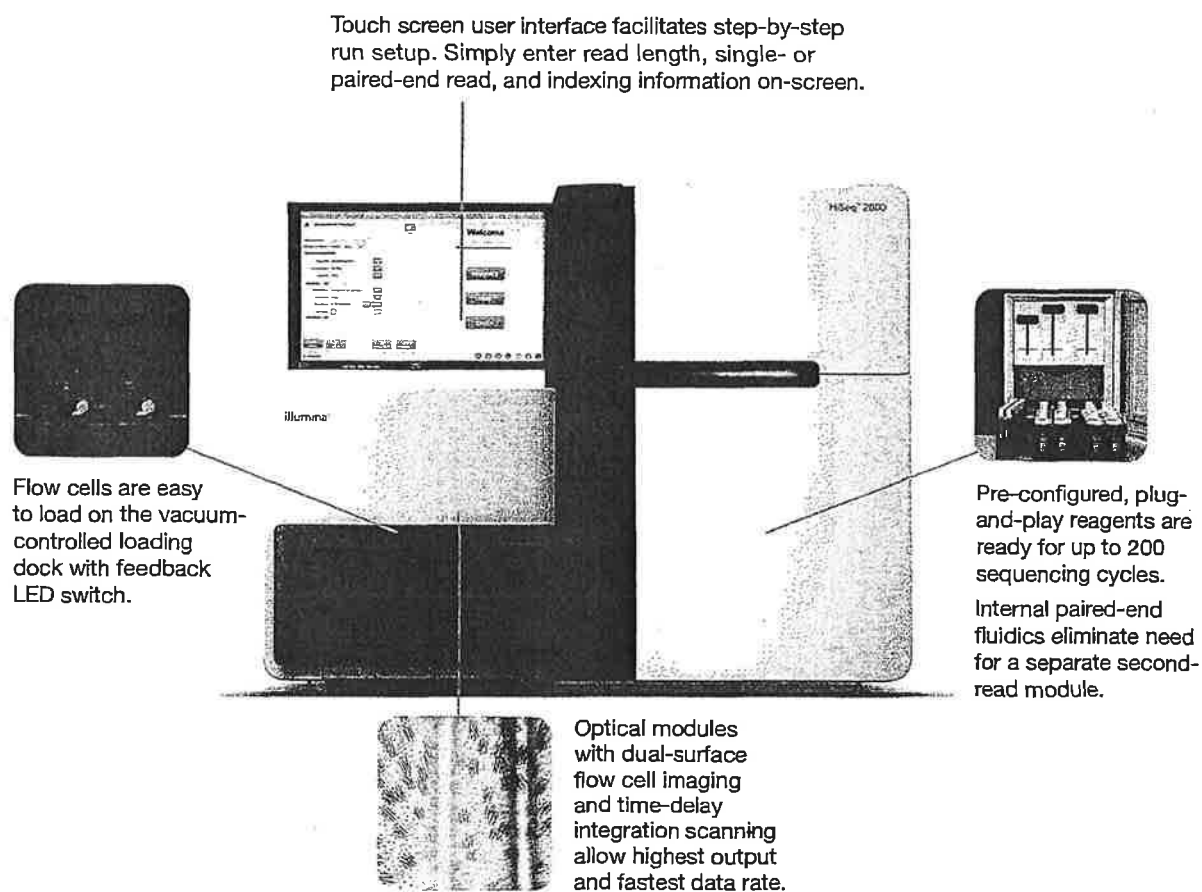
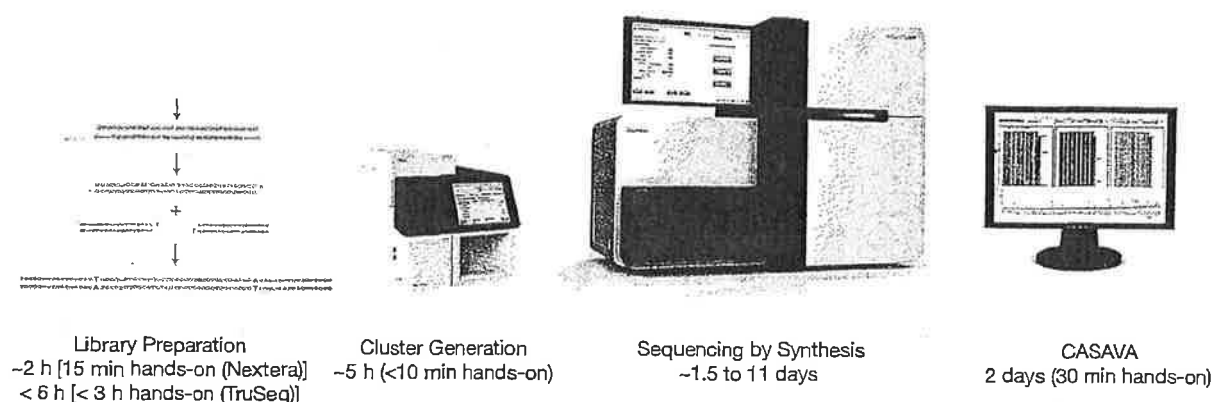


Figure 2: HiSeq 2000 Innovative Design Features



HiSeq Systems redefine the trajectory of sequencing. Innovative engineering and human interaction design features provide a breakthrough user experience and unmatched cost-effectiveness.

Figure 3: Next-Generation Sequencing Simplified



From simplified sample preparation kits and automated cluster generation, to streamlined sequencing by synthesis and complete data analysis, Illumina HiSeq sequencing systems offer the industry's simplest next-generation sequencing workflow.

TruSeq™ Chemistry

The TruSeq family of reagents represents the latest advancement of Illumina's SBS technology. Permeating the entire chemistry workflow, from sample preparation through DNA sequencing, TruSeq underlies Illumina sequencing and empowers it to deliver the industry's most accurate genomic data for a broad range of applications.

SBS technology enables massively parallel sequencing of millions of fragments using a proprietary reversible terminator-based method that detects single bases as they are incorporated into growing DNA strands. A fluorescently-labeled terminator is imaged as each dNTP is added and then cleaved to allow incorporation of the next base. Since all four reversible terminator-bound dNTPs are present during each sequencing cycle, natural competition minimizes incorporation bias. Base calls are made directly from signal intensity measurements during each cycle, which greatly reduces raw error rates compared to other technologies. The end result is highly accurate base-by-base sequencing that eliminates sequence-context specific errors, enabling robust base calling across the genome, including repetitive sequence regions and within homopolymers.

Powered by TruSeq chemistry, Illumina sequencing delivers the most accurate human genome at any level of coverage. The highest yield of error-free reads and most base calls above Q30 provide researchers the highest confidence in their data integrity to draw sound biological conclusions.

Easiest Sequencing Workflow

The Illumina sequencing workflow is based on three simple steps: libraries are prepared from virtually any nucleic acid sample, amplified to produce clonal clusters, and sequenced using massively parallel synthesis. Library preparation can be performed using Illumina's simplified TruSeq sample prep kits or Nextera's Illumina sequencer-compatible DNA Sample Prep Kits. Cluster generation occurs on the cBot automated cluster generation system, where hands-on time is less than ten minutes, compared to more than six hours of hands-on effort for emulsion PCR methods. The process of creating sequencing templates is complete in about four hours per flow cell. For sequencing, either

one or two flow cells can be loaded on HiSeq 2000, enabling different experimental conditions to be run simultaneously. Pre-configured sequencing reagents are dropped in the instrument reagent racks prior to the start of the run.

Streamlined Data Analysis Solution

Accompanying the unprecedented sequencing output of HiSeq 2000 and HiSeq 1000 is Illumina's data analysis solution for transforming billions of bases of raw sequencing data into publishable, biologically meaningful results. HiSeq Control Software offers real-time analysis processing that automatically produces image intensities and quality-scored base calls on the instrument computer for alignment to a reference sequence and subsequent analysis. In combination with the Consensus Assessment of Sequence and Variation (CASAVA) software, GenomeStudio® data analysis software provides intuitive, graphical analysis. The optional IlluminaCompute system is available as a comprehensive and scalable computing architecture for genomic data processing and analysis. IlluminaCompute is an individually configured, pre-packaged data analysis solution consisting of scalable processing, scale-out storage, and comprehensive support for installation, training, and maintenance.

Installation and Support

Comprehensive installation and training is included with every HiSeq System purchase, along with on-going technical support, maintenance and service. Illumina's industry-leading support is available in North America, Europe, and Asia.

Easy Upgrade Path

HiSeq 1000 provides another entry point into the world of HiSeq high-performance sequencing, providing the scalability needed to accommodate expanding sequencing needs. HiSeq 1000 instrument upgrades are performed on-site, quickly transforming the system to a HiSeq 2000 to deliver the industry's highest sequencing output and fastest data generation rate.

HiSeq System Information

HiSeq System Performance Parameters

Parameters	Single Flow Cell (HiSeq 2000 or 1000)*		Dual Flow Cell (HiSeq 2000 only)	
Read Length	Run Time	Output	Run Time	Output
1 × 35 bp	~1.5 days	47–52 Gb	~2 days	95–105 Gb
2 × 50 bp	~4.5 days	135–150 Gb	~5.5 days	270–300 Gb
2 × 100 bp	~8.5 days	270–300 Gb	~11 days	540–600 Gb
Reads	Up to 1.5 billion clusters passing filter, and up to 3 billion paired-end reads		Up to 3 billion clusters passing filter, and up to 6 billion paired-end reads.	
Throughput	Up to 35 Gb per day for a 2 × 100 bp run		Up to 55 Gb per day for a 2 × 100 bp run	
Performance	Greater than 85% bases higher than Q30 at 2 × 50 bp† Greater than 80% bases higher than Q30 at 2 × 100 bp†			

*HiSeq 2000 can be run as a single flow cell or dual flow cell system.

†Install specifications for HiSeq sequencers with an Illumina Phix library and cluster densities between 610 – 678 K/mm² that pass filtering on a HiSeq system using TruSeq v3 Cluster and SBS kits for HiSeq. Performance may vary based on sample quality, cluster density, and other experimental factors. Paired 100 bp runs may vary in the range of 80 to 90% of bases above Q30 and paired 50 bp runs typically vary in the range of 65 to 95% bases above Q30 based on the above factors.

HiSeq System Specifications with Monitor and PC

Instrument Configuration

Computer and touch screen display
Installation setup and accessories
Data collection and analysis software

Instrument Control Computer

Base Unit: 2x Intel Xeon X5560 2.8 GHz CPU
Memory: 48 GB RAM
Hard Drive: 4x 1.0 TB 7200 RPM SATA
Operating System: Windows Vista

Note: Computer specifications will be regularly upgraded.
Contact your local account manager for current configuration.

Operating Environment

Temperature: 22°C ± 3°C
Humidity: Non-condensing 20%–80%
Altitude: Less than 2,000 m (6,500 ft)
Air Quality: Pollution degree rating of II
Ventilation: Maximum of 4,000 BTU/h
For Indoor Use Only

Laser

532 nm, 660 nm, 650 nm (barcode reader)

Dimensions

WxDxH: 118.6 cm × 76.0 cm × 94.0 cm (46.7 in × 30.0 in × 37.0 in)
Weight: 221.4 kg (488 lbs)
Crated Weight: 312 kg (688 lbs)

Power Requirements

100–240V AC 50/60Hz, 20A, 1500W
Illumina provides a region-specific uninterruptible power supply for all HiSeq instruments.

Product Safety

CE marked and ETL listed instrument

HiSeq Systems and Accessories

	Catalog No.
HiSeq 2000 Sequencing System	SY-401-1001
HiSeq 1000 Sequencing System	SY-405-1001
HiSeq 1000 to HiSeq 2000 Upgrade	SY-405-1002
cBot Clonal Amplification System	SY-301-2002

Accelerate Your Research with HiSeq Systems

HiSeq Systems redefine the trajectory of sequencing by combining innovative engineering with proven SBS chemistry to set new standards for output, simplicity, and cost-effectiveness. With the HiSeq 2000 and HiSeq 1000, the ability to process larger numbers of samples and to decode larger and more complex genomes means that virtually any sequencing project is now within reach.

Learn More

For more information about HiSeq 2000, HiSeq 1000, and Illumina sequencing, visit www.illumina.com/systems.

MiSeq® System

Fully integrated, next-generation sequencing ecosystem for rapid genetic analysis.

MiSeq System Highlights

- **Sequencing at the touch of a button**
Integrated and automated system requires no intervention, eliminating potential error
- **Most rapid variant detection for time-critical studies**
Go from DNA to data in less than 8 hours
- **Proven data quality**
Leverages the industry's most accurate TruSeq® chemistry for the highest confidence in your data
- **Optimized for key applications**
Adjustable read lengths and imageable area provide ultimate experimental flexibility across a broad range of applications

Introduction

The MiSeq personal sequencing system enables researchers to go from sample to analyzed data in as little as eight hours with a revolutionary workflow and unmatched accuracy. Capable of generating up to 7.0 Gb per run, MiSeq is the only next-generation sequencer that integrates amplification, sequencing, and data analysis in a single instrument with a footprint of approximately 2 feet square (Figure 1). In contrast to sequencing systems that require emulsion PCR, the MiSeq system leverages Illumina's proven TruSeq chemistry, making it the ideal platform for any lab performing rapid and cost-effective genetic analysis for the widest range of applications.

Push Button Sequencing

The MiSeq system offers the easiest next-generation sequencing workflow. Perform simple instrument operation with an intuitive touch screen interface and plug-and-play reagents with RFID tracking and automated convenience. The compact, all-in-one MiSeq platform incorporates cluster generation, paired-end fluidics, and complete data analysis, eliminating the need for auxiliary hardware and saving valuable lab bench space. Seamless data upload to the BaseSpace™ cloud environment enables unparalleled analysis, collaboration, and security.

Fastest Turnaround Time

For results in hours rather than days, the MiSeq system delivers the simplest and fastest turnaround time of any next-generation personal sequencing system (Figure 2). Prepare your sequencing library in just 90 minutes with Nextera® sample prep reagents, then move to automated clonal amplification and sequencing in as little as three and a half hours directly on the MiSeq system. On the integrated instrument computer, data analysis from quality-scored base calls to variant calling and alignment is complete in less than two hours with no user intervention.

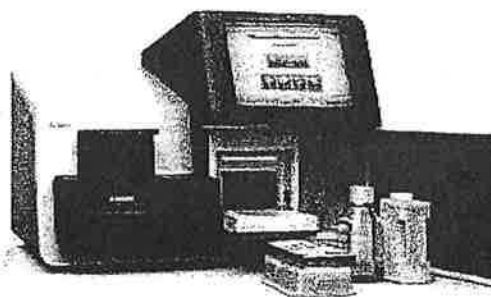
Proven Data Quality

Based on Illumina's proven sequencing by synthesis technology, massively parallel sequencing of millions of fragments occurs by a proprietary reversible terminator-based method that detects single bases as they are incorporated into growing DNA strands. A fluorescently labeled terminator is imaged as each dNTP is added and then cleaved to allow incorporation of the next base. Since all four reversible terminator-bound dNTPs are present during each sequencing cycle, natural competition minimizes incorporation bias. Base calls are made directly from signal intensity measurements during each cycle, greatly reducing raw error rates compared to other technologies. The end result is highly accurate base-by-base sequencing that eliminates sequence context-specific errors, enabling robust base calling, even within repetitive sequence regions and homopolymers. Illumina sequencing is powered by TruSeq technology, and delivers the highest data integrity, with the highest yield of error-free reads and the most base calls above Q30.

Optimized for Key Applications

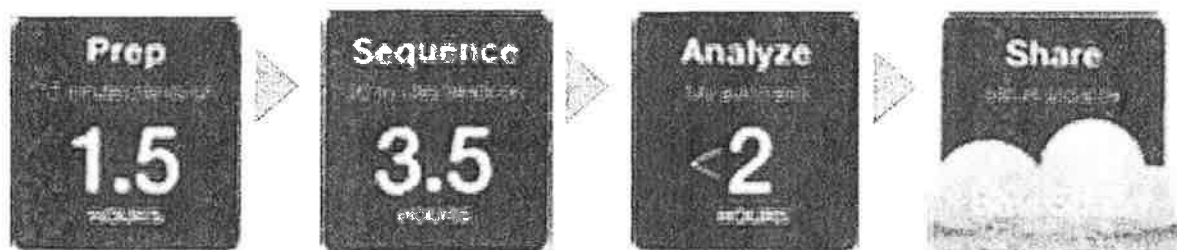
Explore the broadest range of sequencing applications. Adjustable read lengths and imageable area and the choice of single or paired-end reads allow you to match experimental needs to your time requirements. Perform rapid and cost-effective capillary electrophoresis (CE) sequencing applications, as well as highly multiplexed amplicon sequencing with TruSeq Custom Amplicon, TruSeq Custom Enrichment, small genome resequencing and *de novo* sequencing, small RNA sequencing, library QC, and 16S metagenomics studies. For current next-generation sequencing users, complete sequencing projects in a fraction of time and cost using the MiSeq system.

Figure 1: MiSeq System



Illumina's compact MiSeq system is the ideal platform for rapid, cost-effective next-generation sequencing.

Figure 2: MiSeq Workflow



The MiSeq system's revolutionary workflow enables the fastest turnaround time of any next-generation personal sequencing system.

MiSeq System Performance Parameters

Read Length	Total Time from Prepped Library through Sequencing*	Output
1 x 35 bp	3.2–3.5 hours	440–550 Mb
2 x 25 bp	4.6–5.0 hours	640–800 Mb
2 x 100 bp	14.0–16.0 hours	2.5–3.1 Gb
2 x 150 bp	20.7–24.0 hours	3.7–4.6 Gb
2 x 250 bp**	>35 hours	6.0–7.0 Gb
Reads	12.0–15.0 million clusters passing filter, and 24.0–30.0 million paired-end reads	
Performance†	>90% bases higher than Q30 at 1 x 35 bp >90% bases higher than Q30 at 2 x 25 bp >85% bases higher than Q30 at 2 x 100 bp >75% bases higher than Q30 at 2 x 150 bp	

* Includes paired-end read, if applicable.

**Performance, output, amplification, and sequencing time for 2 x 250 bp read length depends on instrument upgrade, commercially available in the third quarter of 2012. Customers will be notified of upgrade availability. Upgrade dates are subject to change.

†The percentage of bases >Q30 is averaged across the entire run, not on a per-read or per-cycle basis.

Ordering Information

	Catalog No.
MiSeq system	SY-410-1001

Learn More

Go to www.illumina.com/miseq to learn more about the next revolution in personal sequencing.

MiSeq System Specifications

Instrument Configuration

RFID tracking for consumables

MiSeq Control Software

MiSeq Reporter Software

Instrument Control Computer (Internal)*

Base Unit: Intel Core i7-2710GE 2.10 GHz CPU

Memory: 16 GB RAM

Hard Drive: 750 GB

Operating System: Windows 7 embedded standard

*Computer specifications are subject to change.

Operating Environment

Temperature: 22°C ± 3°C

Humidity: Non-condensing 20%–80%

Altitude: Less than 2,000 m (6,500 ft)

Air Quality: Pollution degree rating of II

Ventilation: Maximum of 1,364 BTU/h

For Indoor Use Only

Light Emitting Diode (LED)

530 nm, 660 nm

Dimensions

WxDxH: 68.6 cm x 56.5 cm x 52.3 cm (27.0 in x 22.2 in x 20.6 in)

Weight: 54.5 kg (120 lbs)

Crated Weight: 90.9 kg (200 lbs)

Power Requirements

100–240V AC @ 50/60Hz, 10A, 400W

Radio Frequency Identifier (RFID)

Frequency: 13.56 MHz

Power: 100 mW

Product Safety and Compliance

NRTL certified IEC 61010-1

CE marked

FCC/IC approved

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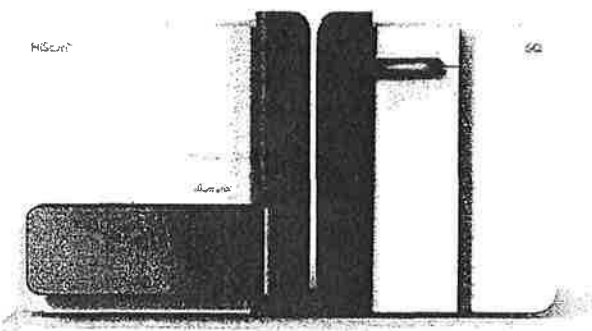


Systems / HiScanSQ

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Protein Analysis	BeadXpress	Illumina Financial Solutions		DesignStudio	Investor Relations
Real-Time PCR	Eco Real-Time PCR System	Illumina Connect		Assay Design Tool	Privacy
AgriGenomics	Software			Product Files	Legal
Cytogenetics	BaseSpace			Eco Real-Time PCR Support	California Transparency in Supply Chain
Cancer Genomics				Customer Service	
				Training	

Innovative technologies

At Illumina, our goal is to apply innovative technologies and revolutionary assays to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. These studies will help make the realization of personalized medicine possible. With such rapid advances in technology taking place, it is mission critical to have solutions that are not only innovative, but flexible, scalable, and complete with industry-leading support and service. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and prioritizing the needs of its customers, we strive to meet this challenge. Illumina's innovative, array-based solutions for DNA, RNA, and protein analysis serve as tools for disease research, drug development, and the development of molecular tests in the clinic.

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Eco

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7-day trial

The Eco Real-Time PCR System

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With the Eco system, Real-Time PCR technology is now within reach of individual researchers. Large, expensive thermal cyclers that take up an entire workspace are replaced with an affordable, compact system on a Netbook computer that fits easily in any lab. Delivering unsurpassed data quality for 40-cycle runs in as little as 40 minutes, the Eco system revolutionizes qPCR accessibility for both new and experienced Real-Time PCR users.

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 - ✓ Relative quantification using $\Delta\Delta\text{Cq}$ method with support for multiple reference gene normalization
 - ✓ Allelic discrimination by end-point fluorescence
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Learn about the Science »

High-performance Real-Time PCR System includes:



- Eco instrument
- Netbook computer pre-installed with Eco software and HRM module
- USB flash drive with Eco software
- Eco sample loading dock
- Starter pack of 10 plates, 40 seals, and one Evaluation Kit

US Price: **Only \$13,900.00!**

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Specifications

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Instrument

Thermal system

Single Peltier-based system

Block format	48-well block
Consumables	48-well Eco plates and optical Eco adhesive seals
Accessories	Eco sample loading dock
Sample volumes	5–20µl validated (optimized for standard 20µl protocols)
Average block ramp rate	5.5°C/sec
Temperature range	35–100°C
Temperature uniformity	± 0.1°C
Optical system	LED excitation (452–486 nm and 542–582 nm), four emission filters (505–545 nm, 562–596 nm, 604–644 nm, and 660–705 nm) and CCD camera
Calibrated dyes at shipment	SYBR, FAM, HEX, ROX, Cy5: factory-calibrated. Additional dyes within wavelength range of Eco filters are supported with no additional calibration required for implementation
Data collection	Data collected in all four filters for all wells regardless of plate setup; plate setup for data analysis can be altered after run completion. Melt curve analysis supports continuous data acquisition in a single channel, providing increased data point collection and reduced run times
Real-Time PCR run time (40 cycles)	Less than 40 minutes
Electrical	Voltage: 120VAC±10% Nominal current draw: 8A Frequency: 50/60 Hz±1% Peak Power 500VA, typical power is 180VA
Software	Eco System Software supports all chemistries and a variety of applications, including absolute quantification, relative quantification, allelic discrimination, and high resolution melt curve analysis (HRM)
Warranty	12-month warranty (includes parts and labor)

Instrument Physical

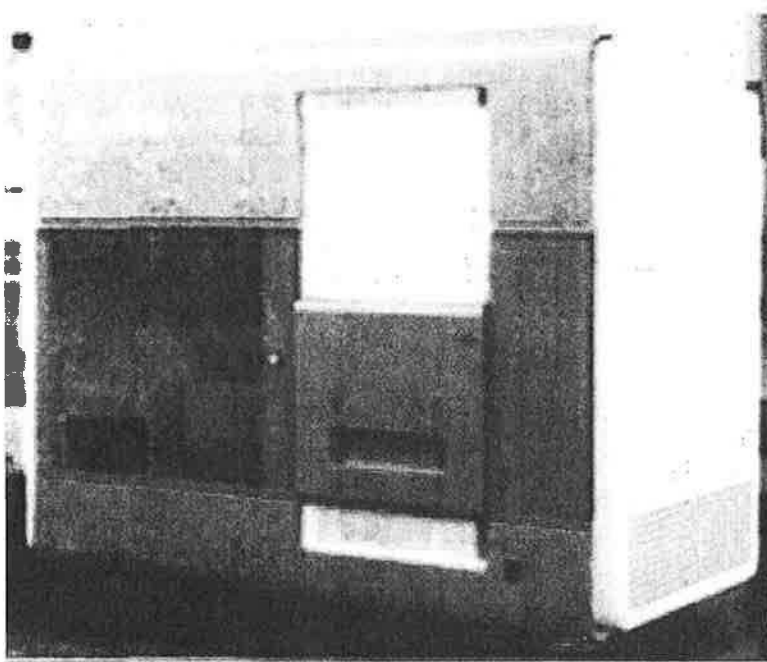
Instrument dimensions	12.6" closed (height) 14.5" open (height) 13.6" (depth) 12.2" (width) 32 cm closed (height) 36.8 cm open (height) 34.5 cm (depth) 31 cm (width)
Weight	30 lbs (13.6 Kg)

Performance

Sensitivity	1 copy
Dynamic range	9 logs linear range
Precision	Discriminates 5,000 and 10,000 template copies with 99% confidence

ILLUM-0839

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technology & applications

overview

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- ☐ genotyping
- ☐ gene expression profiling
- ☐ microarrays
- ☐ background on genetic variation

chemical detection

technology platform

publications & resources

FAQ

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genotyping

SNP (single nucleotide polymorphism) genotyping is the process of determining which point mutations are present in each of the two copies of a gene or other portion of DNA sequence within a human or model organism. The use of genotyping analysis to obtain meaningful statistics on the impact of a single SNP or set of SNPs on individuals and population segments will require billions of tests or assays. Test scales may require, for example, 100,000 assays per individual for 1000 or more individuals involved in typical clinical trial.

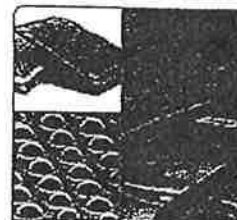
Large-scale SNP genotyping, when commercially feasible, will be used for a variety of applications, including genomics-based drug development, clinical trial analysis, disease predisposition testing, and disease diagnosis. SNP genotyping can also be used outside of healthcare, for example in the selection and breeding of plants and animals with desirable commercial characteristics. These markets will require billions of SNP genotyping assays.

Our First Offerings

Illumina has partnered with Applied Biosystems Group to develop integrated solutions for high throughput SNP genotyping. The offering will include disposable Bead Array cassettes, reagent kits, instruments and related software.

SNP Genotyping Services

Our BeadArrayTM platform and an advanced LIMS environment provide high-throughput, accuracy and control to lower your genotyping cost per call. [Learn more](#)



Illumina is developing a high-throughput SNP genotyping application.

NEWS & HIGHLIGHT

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services: genomic services with solexa sequencing technology

Even without a platform commitment, you can leverage the power of Solexa sequencing technology through our Illumina's Genomic Services. With years of experience delivering high-quality service, we offer a range of consultative and analytical capabilities, which can be tailored to meet your needs. Our proven track record of successfully executing high-value projects, and the access we provide to a team of seasoned professionals, will make using sequencing-by-synthesis technology convenient and affordable. Rely on Illumina's Genomics Services group to design and complete your projects in record time and at costs that no other technology can match.

applications offered

- Candidate gene and region resequencing
- Bacterial DNA resequencing
- Digital expression profiling
- Small RNA discovery

If your application of interest does not appear on the list, please contact us. We can often work with you to design the appropriate protocols and processes to handle your application.

The Genomics Services group can provide you with assistance across your entire workflow:

- Consultation on experimental design
- Sample preparation and QC
- Cluster generation
- Sequencing-by-synthesis using the Illumina Genome Analyzer
- Data analysis and bioinformatics consultation



important in

- product literature
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TruSeq™ SBS Kit-HS (200 cycles)

Box 2 of 2

BOX.HI SEQ_SEQUENCING_BX2

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2010-07-16



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San Diego, CA 92121 USA

-15°C
-25°C

Label PN: 15010460.C

Patent Numbers: 7,957,026, 7,414,116, 7,427,673, 7,541,444, 7,592,435

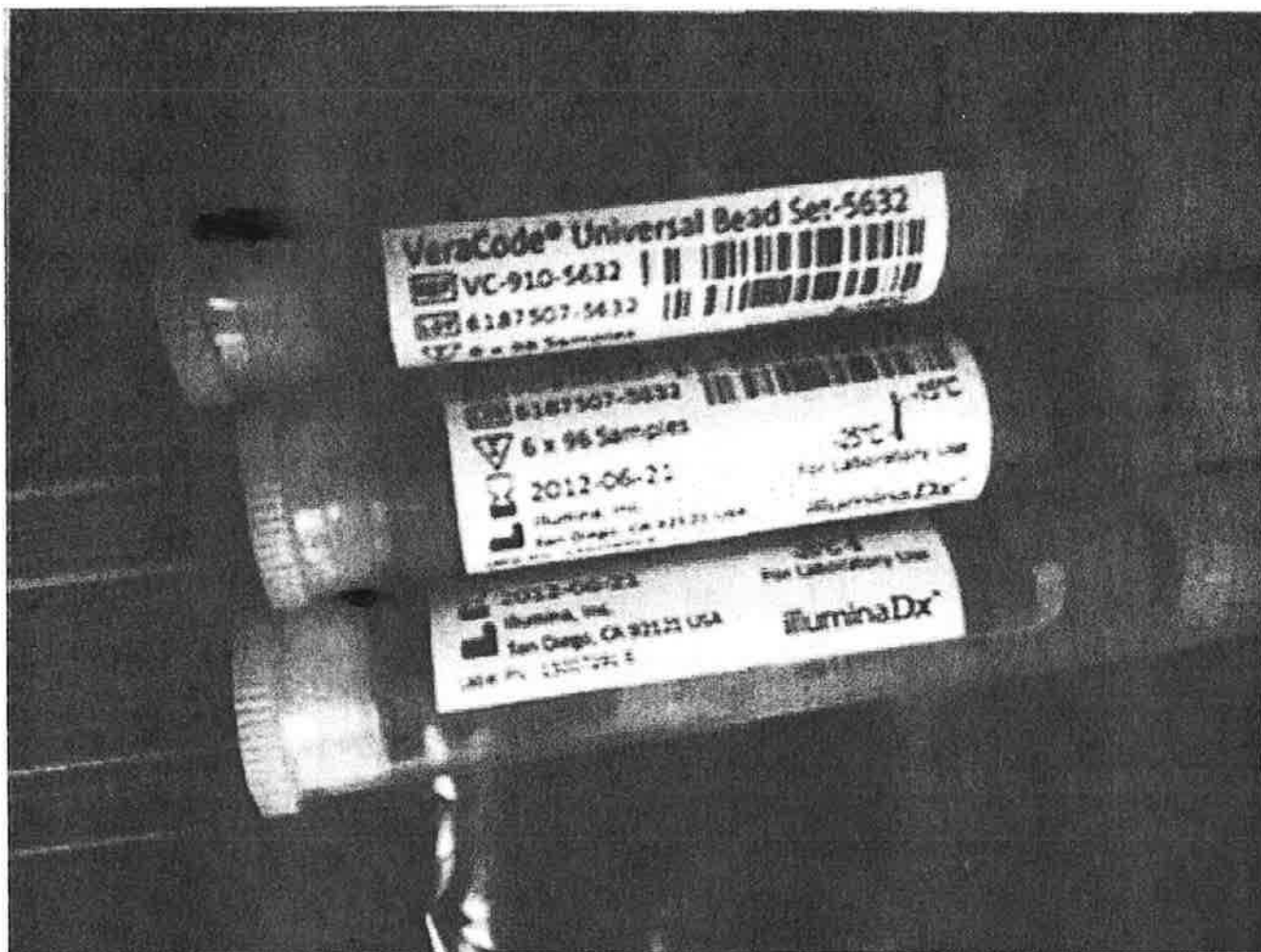
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Whole-Genome DASL® HT DAP- 24 Sample

BAG.DAP WG-DASL HT,HT12,v4,24

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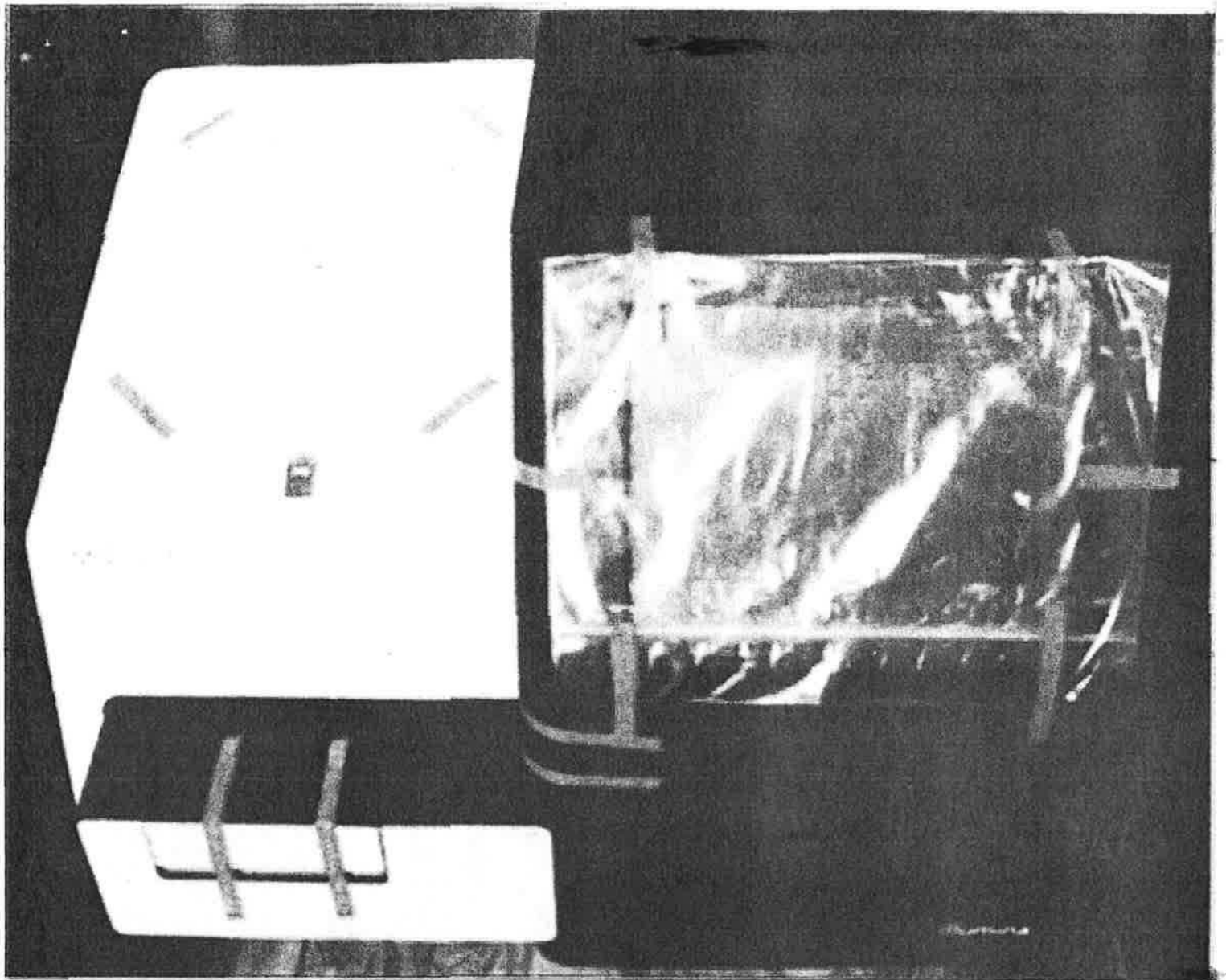
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ILLUM-0848

GenomeStudio™ Genotyping Module v1.0 Application & Documentation

Part # 11319324



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Illumina® FastTrack Genotyping Services

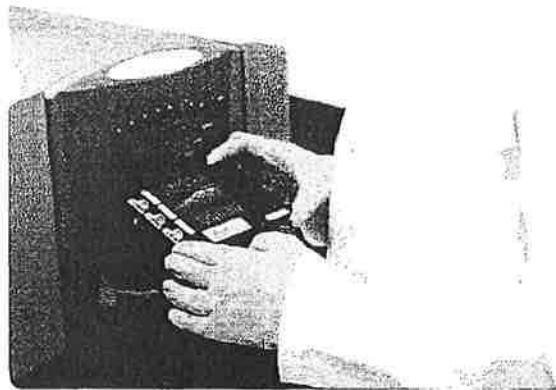
Experience personalized service, industry-leading data quality, and guaranteed turnaround time with Illumina's FastTrack Genotyping Services for a wide range of SNP genotyping projects.

"Overall, our experience working with Illumina has been simply outstanding. The scientific and service staff of this organization are highly talented and committed individuals... The staff of Illumina went well beyond the normal service requirement in order to maximize information yield on these samples."

PETER K. GREGERSON, M.D., Center Head, The Robert S. Boas Center for Genomics and Human Genetics

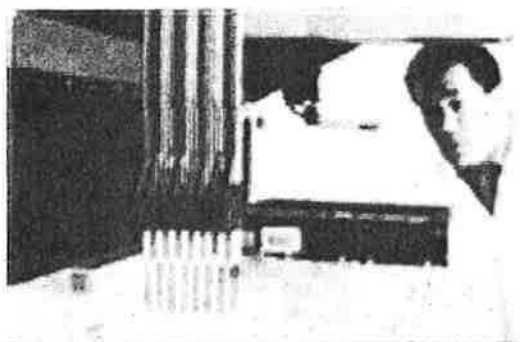
At Illumina, we work collaboratively with you to achieve your research objectives. Using Illumina's cutting-edge SNP genotyping technology, our in-house geneticists have consistently provided on-time, reliable genotyping services to academic and pharmaceutical customers since 2002. In collaboration with our customers, we have provided data for the study of many diseases through services projects, from various cancers to diabetes and schizophrenia. Using Illumina's FastTrack Services gives you the same competitive advantages as our installed base of customers: the ability to conduct whole-genome association studies, DNA copy number studies, linkage analysis, and fine mapping studies in a timely fashion at a reasonable cost.

In addition to the benefits you can realize by outsourcing your discovery efforts, you will also appreciate the professional design assistance and collaborative approach Illumina has proudly delivered since program inception. We highly value the quality outcome of your projects as much as your experience working with us.

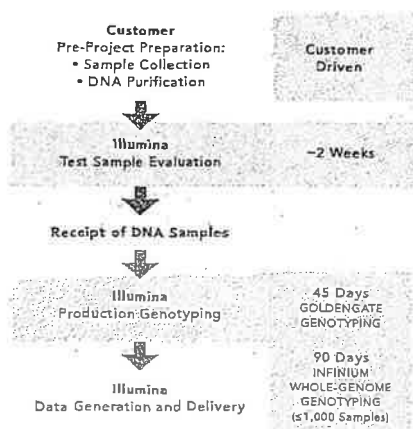


KEY HIGHLIGHTS OF PAST PERFORMANCE

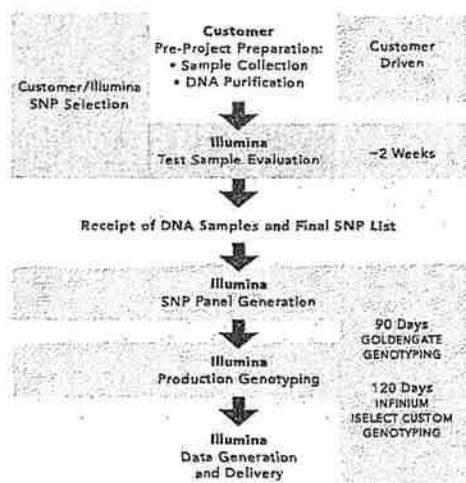
- **Infinium® Service Projects:**
Sample Success Rate: 99.5%
Call Rate: 99.89%
- **GoldenGate® Service Projects:**
DNA Success Rate: 97.6%
Call Rate: 99.75%



STANDARD PANEL GENOTYPING PROJECT TIMELINE



CUSTOM PANEL GENOTYPING PROJECT TIMELINE



PERSONALIZED SERVICE WITH DEDICATED EXPERTS

- An expert molecular geneticist project manager assigned to each project
- Project completion and success ensured with guaranteed fast delivery
- Intensive customer engagement with proven process flow driven by best practices
- Each project dataset reviewed and QC'd by the services group
- Every sample and every SNP locus assigned a quality score
- Streamlined custom SNP selection from an up-to-date database of >1 million validated SNP markers
- Final annotated SNP lists specified with expected assay conversion rates

RELIABLE, PROVEN, FAST, AND ROBUST PROCESS

- Over 200 projects between 2002 and 2006, all delivered on time
- Guaranteed delivery date, with average study turnaround time <90 days
- Over 200,000 DNA samples genotyped, with nearly 100% success
- World-class Illumina BeadLab environment capable of generating over 75 million genotypes per day
- Expertise with large datasets—over 1 billion genotypes delivered for a single customer project
- Fully integrated custom Laboratory Information Management System (LIMS) tracking from sample input to data output and analysis
- Barcoded plates sent to customers to ensure accurate sample tracking
- Streamlined process for safe and secure dry ice sample shipment

INDUSTRY-LEADING DATA QUALITY

- Consistently impressive results from best-performing genotyping products, quality-driven processes, and professional expertise
- Maximal information value at every locus
- Illumina control samples included on every sample plate for extensive real-time QC and data review in LIMS environment
- Low sample input requirements

COMPREHENSIVE STUDY TYPES

- Industry's most flexible and comprehensive portfolio with Infinium and GoldenGate assays
- Standard and custom content
- Whole-genome and fine mapping studies
- Scalable multiplex levels—from 384 custom SNPs to 1 million standard SNPs per assay
- Wide sample size range—from 300 to several thousand
- Tag SNP selection available for any combination of the four HapMap populations
- All organisms supported; extensive experience with organisms such as human, cow, pig, chicken, mouse, dog, and corn
- Seamless transition to follow-on projects—from Infinium Whole-Genome Genotyping to iSelect Custom Genotyping, and then to targeted panels with Custom GoldenGate Genotyping—all with the same trusted team, quality data, and LIMS-driven process

SUMMARY

Take advantage of Illumina's full menu of FastTrack Genotyping Services. Our highly experienced FastTrack Project Managers are committed to working collaboratively with you from beginning to end, to ensure the highest quality data and fast turnaround. Enjoy the benefits of innovative technologies and personalized service from the genotyping market leader.

INFINIUM WHOLE-GENOME GENOTYPING
PAST PERFORMANCE*

(Based on all contracts between January and September 2006
>11,500 BeadChips and 3.5 billion genotypes)

Infinium Service Projects	Average
Sample Success Rate	99.47%
Locus Success Rate	99.11%
Call Rate	99.89%
Reproducibility	99.99%
Heritability (Trios)	99.98%

* Performance for individual studies varies and depends on the DNA quality of the samples submitted and the quality of the SNPs selected

GOLDENGATE PAST PERFORMANCE*

Based on all contracts between January 2005 and June 2006
(>150,000 individual DNA samples from 100 projects)

GoldenGate Service Projects	Average
Custom Assay Development Success	
- Human only	92.8%
- All species	91.2%
DNA Success Rate	97.6%
Call Rate	99.75%
Reproducibility	>99.99%
Heritability	>99.99%

* Performance for individual studies varies and depends on the DNA quality of the samples submitted and the quality of the SNPs selected

NUMBER OF LOCI ASSAYED AND TURNAROUND TIME REQUIRED FOR FASTTRACK GENOTYPING SERVICES TO PROCESS STANDARD AND CUSTOM PANELS

Standard Panels	Number of Loci	Guaranteed Turnaround Time
GoldenGate Genotyping	~30–6000	45 days ¹
Infinium Whole-Genome Genotyping	300,000–1,000,000	90 days ^{1,2}
Custom Panels		
Custom GoldenGate Genotyping	384–8,000+	90 days ³
Infinium iSelect™ Custom Genotyping	7,600–60,800	120 days ³
Infinium Semi-Custom HumanHap300-Duo+ Genotyping	7,600–60,800 ⁴	120 days ^{2,3}
Infinium Semi-Custom HumanHap550+ Genotyping	7,600–121,600 ⁵	120 days ^{2,3}

¹From DNA sample submission

²For up to 1,000 samples

³From date of final SNP list and DNA sample submission

⁴Add 7,600–60,800 custom loci to standard 300,000 loci per sample

⁵Add 7,600–121,600 custom loci to standard 550,000 loci

ORDERING INFORMATION

FASTTRACK GENOTYPING SERVICES STANDARD PANEL PROJECTS

CATALOG #	PRODUCT	Number of Loci	DNA Required per Sample (µg)	Volume Required per Sample (µl)
	Infinium Whole-Genome Genotyping Standard Panel Service Project			
FT-20-101	HumanHap300-Duo Genotyping BeadChip	>300,000	3	60
FT-20-102	HumanHap2405-Duo Genotyping BeadChip	>240,000	3	60
FT-20-104	HumanHap550 Genotyping BeadChip	>550,000	3	60
FT-20-105	HumanHap650Y Genotyping BeadChip	>650,000	3	60
FT-20-106	HumanHap450S DNA Analysis BeadChip	>450,000	3	60
FT-20-107	Human1M DNA Analysis BeadChip	>1,000,000	3	60
FT-20-108	HumanCNV370-Duo DNA Analysis BeadChip	>370,000	3	60
FT-20-111	HumanLinkage-12 DNA Analysis BeadChip	>6,000	1.5	30
FT-20-109 ^a	BovineSNP50 Genotyping BeadChip	>50,000	1.5	30
FT-20-110 ^a	CanineSNP20 Genotyping BeadChip	>20,000	1.5	30
FT-20-113 ^a	CVDSNP60 Genotyping BeadChip	>60,000	1.5	30
FT-10-101	GoldenGate Genotyping Standard Panel Service Project			
	Linkage V Panel	6,056	4	80
	Mouse LD Linkage	377	2	40
	Mouse MD Linkage	1,449	2	40
	MHC Panel Set	2,360	4	80
	MHC Mapping Panel	1,293	2	40
	MHC Exon-Centric Panel	1,228	2	40
	Cancer SNP Panel	1,421	2	40

^aThese products are currently available for ordering, but will not be in use until late 2007

FASTTRACK GENOTYPING SERVICES CUSTOM PANEL PROJECTS

CATALOG #	PRODUCT	Number of Loci	DNA Required per Sample (µg)	Volume Required per Sample (µl)
FT-15-101	Custom GoldenGate Genotyping Project	up to 1,536 1,632–4,608 4,704–9,216	2 4 6	40 80 120
FT-25-101	Infinium iSelect Custom Genotyping Project	7,600–60,800	1.5	30
FT-25-102	Infinium Semi-Custom HumanHap300-Duo+ Genotyping Project	7,600–60,800 ^a	3	60
FT-25-103	Infinium Semi-Custom HumanHap550+ Genotyping Project	7,600–121,600 ^a	3	60

^aAdd 7,600–60,800 custom loci to the standard 300,000 loci per sample on the HumanHap300-Duo Genotyping BeadChip

^aAdd 7,600–121,600 custom loci to the standard 550,000 loci on the HumanHap550 Genotyping BeadChip

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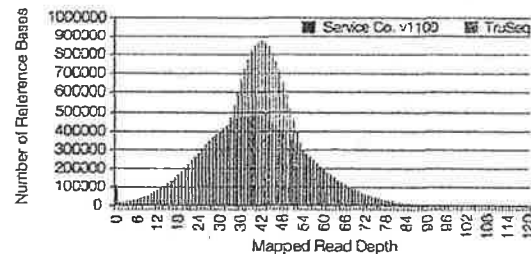
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The Illumina Genome Network

The Illumina Genome Network links researchers interested in conducting large whole human genome sequencing projects with leading institutes worldwide that provide highly economical and rapid turnaround access to Illumina sequencing. Consisting of CSPro-certified organizations with proven expertise in generating high-quality, economical human genome data, the Illumina Genome Network enables researchers to complete their genome sequencing projects rapidly and confidently. Highest quality data with fast turnaround times: that is the promise of the Illumina Genome Network.

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- High quality variant calling of single nucleotide polymorphisms (SNPs) and insertions and deletions (Indels)
- Ability to identify Copy Number Variations (CNV) and other structural rearrangements
- Access to a comprehensive set of in-house and third-party analysis tools designed to support the system with the largest installed base in the industry
- Ability to reanalyze data sets over time

You can choose your Illumina Genome Network partner and create service packages based on your individual study requirements. Flexible turnaround times and a range of value-added services are available to meet the unique needs of every study. It's a quick and reliable way to get your sequencing study started on the Illumina sequencing technology platform.

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Whole Human Genome Sequencing Services Brochure
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Technical Note-Leveraging Whole Human Genome Sequencing in Cancer

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Applications	Systems	Services	Science	Support	Company
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Protein Analysis	Software BaseSpace	Illumina Connect	Eco Real-Time PCR Support	In Supply Chain
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Cytogenetics				
Cancer Genomics				

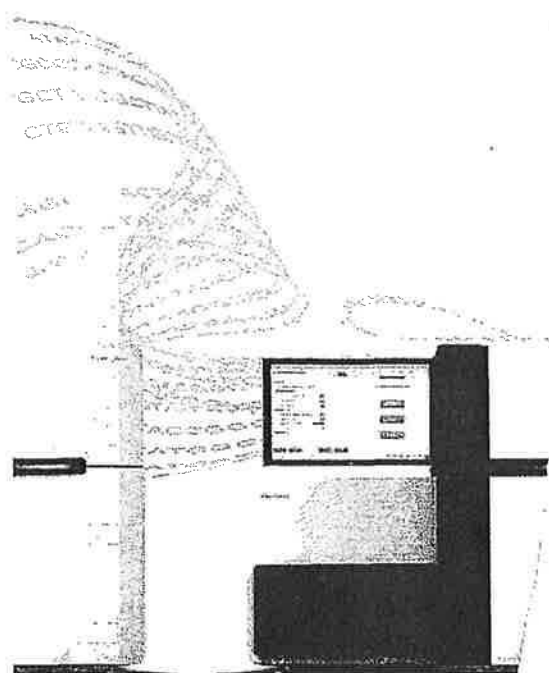
Innovative technologies

At Illumina, our goal is to apply innovative technologies and revolutionary assays to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. These studies will help make the realization of personalized medicine possible. With such rapid advances in technology taking place, it is mission critical to have solutions that are not only innovative, but flexible, scalable, and complete with industry-leading support and service. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and prioritizing the needs of its customers, we strive to meet this challenge. Illumina's innovative, array-based solutions for DNA, RNA, and protein analysis serve as tools for disease research, drug development, and the development of molecular tests in the clinic.

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Whole human genome sequencing services.

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Certified service labs producing validated Illumina data.

Whole human genome sequencing services. Without compromise.

When you use the Illumina Genome Network, you get the highest data quality with the fastest turnaround, to decrease your time-to-publish. All of your data is delivered in industry-standard format to streamline collaborations and allow integrated follow-on studies. And everything is completed at a competitive price, so you can sequence more samples for less.

The Illumina Genome Network delivers the following key analysis results and metrics:

- **Sequence data:** Aligned and non-aligned reads in archival BAM format
- **Variant information:** SNP, indel, CNV, and SV (e.g., large insertion, large deletion) variant calls in VCF format
- **Sample report:** Summary of sample and genome quality metrics in PDF format
- **SNP concordance:** All genotyping and WGS data files are provided (Figure 1)

Greater confidence in results.

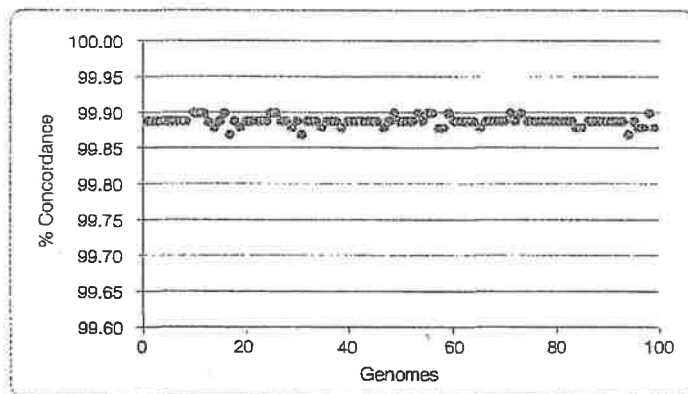


Figure 1. Independent confirmation with HumanOmni 2.5 BeadChip shows SNP concordance > 99% for every sample.

Proven TruSeq technology. Most accurate genome at any coverage.

Illumina platforms make up the largest installed base of next-generation sequencing systems worldwide—referenced in over 2,100 peer-reviewed publications, and counting. They're the most trusted and widely adopted for a reason: our proven TruSeq technology, delivering the highest data accuracy in the industry for variant calling (Figure 2).

Whole-genome sequencing involves more than obtaining high coverage depth and quality reads. That's why we run each base pair through a usable genome test (Figure 3), resulting in the highest callable genome with quality scores of Q30 or more on > 80% of all reads passing filter. This holds true even within the difficult-to-sequence regions of the genome.

Highest accuracy. More usable data.

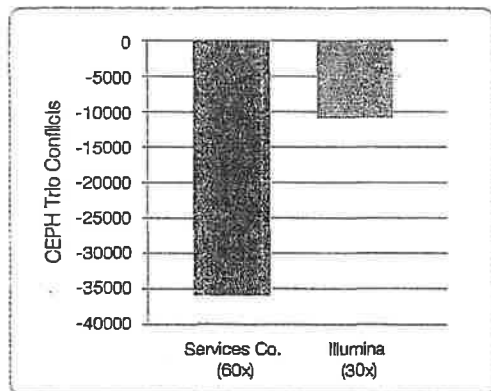


Figure 2. Services Co. data contains over 35,000 consensus conflicts or errors within the genome.

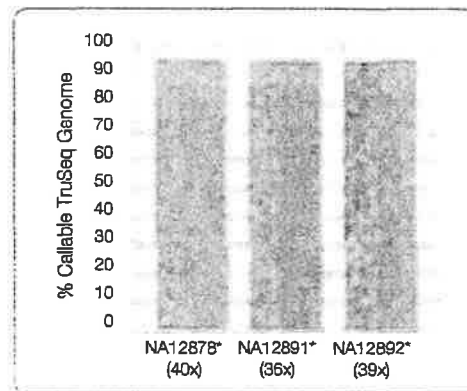


Figure 3. More usable data: > 95% of the NCBI reference genome.

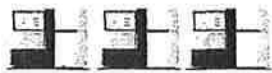
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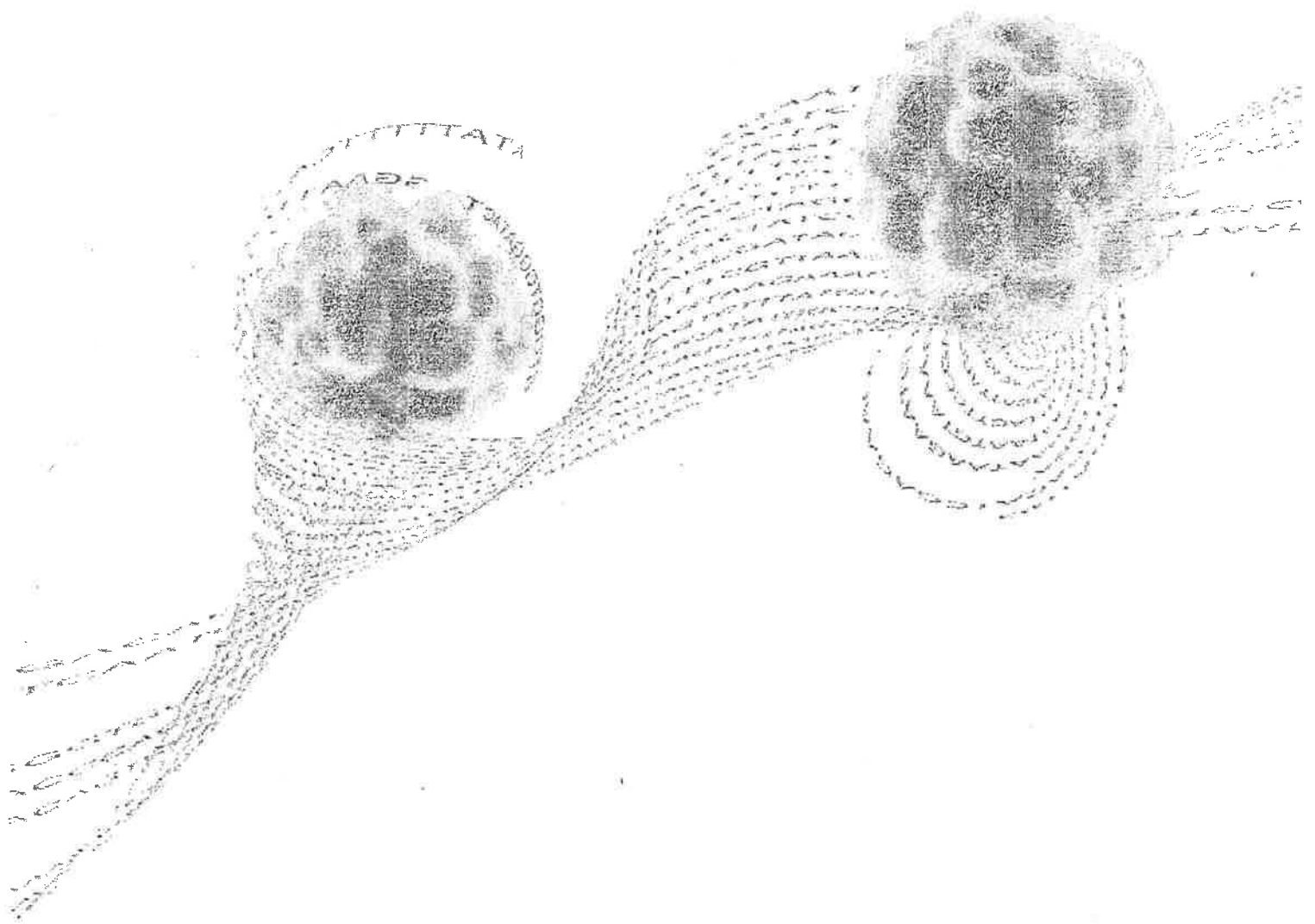
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Cancer Genomics

Transforming our
understanding of cancer

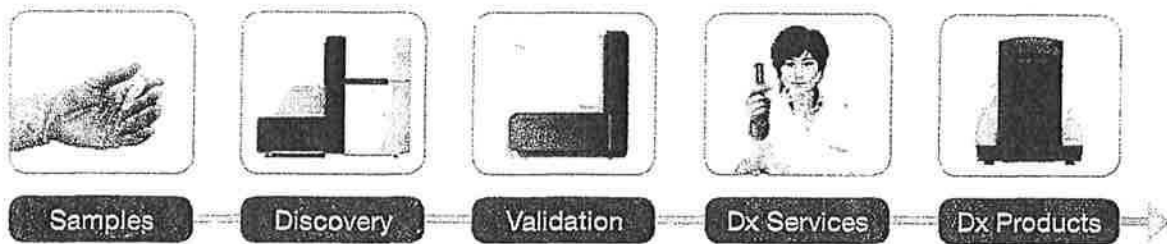


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Technology enhances understanding. Drives discovery.

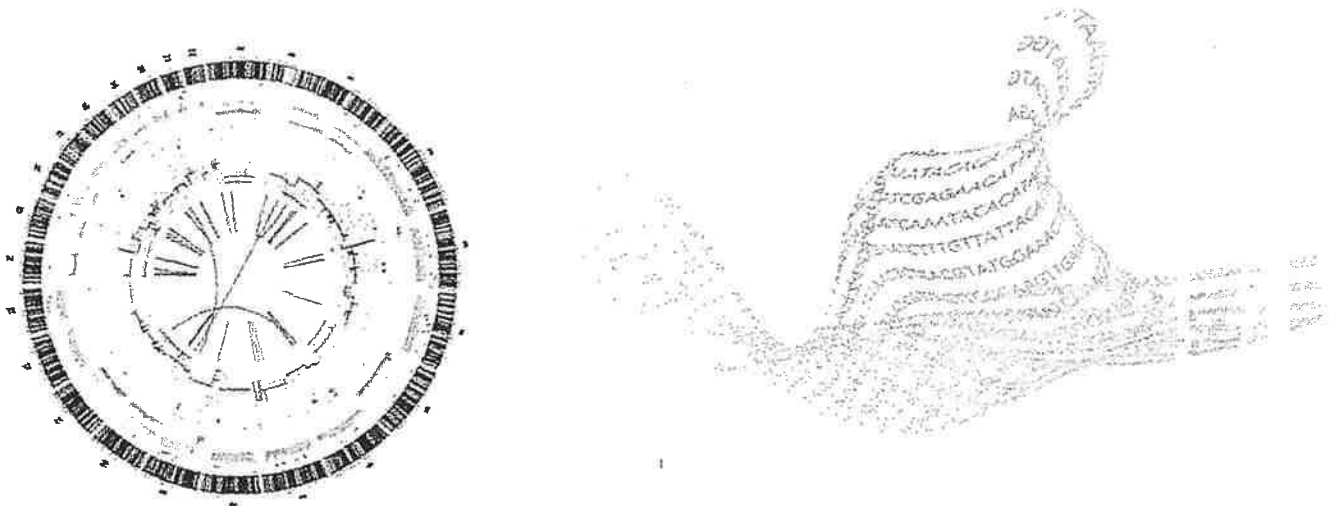


Illumina's cancer discovery initiative.

Our belief in the power of Illumina technology is so strong that we work side by side with researchers to obtain samples for our cancer discovery work. Using whole-genome sequencing, we are exploring how biomarker discovery can lead to early detection, resistance to therapy, and prognosis in ovarian, gastric, and colorectal cancer. Discovering how analyzing subtle changes in genes and chromosomes will change diagnostics forever. Ultimately leading to novel diagnostic services and products as shown in the continuum above.

Illumina's clinical services lab.

Innovative. Comprehensive. The first choice for doctor-ordered Individual Genome Sequencing services. The first to generate a complete human sequence in a clinical laboratory. Fully CLIA-certified and CAP-accredited for high-complexity molecular testing.



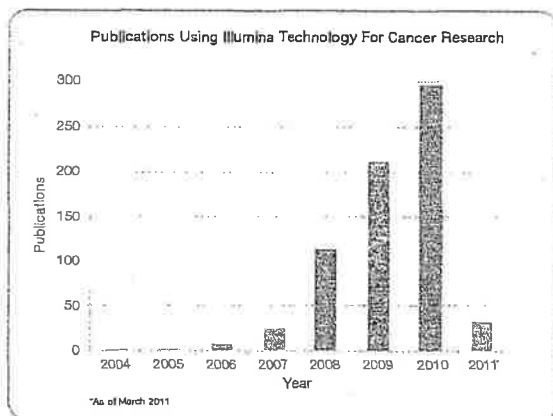
When taking a genome-wide approach to cancer, researchers can use a circus plot to visualize the extensive rearrangements and variations that are common to cancer. This plot shows variations found in a melanoma cell line, marking each chromosome on the outside ring, then showing validated indels, density of substitutions, coding substitutions, copy number variants, loss of heterozygosity, to reveal the intrachromosomal and interchromosomal structural variants in the middle of the plot.

Empowering cancer research.

Sequencing. Microarrays. Real-time PCR. Technology is fueling a new era of cancer discovery and validation.

The growing Illumina community is a part of this revolution. Taking advantage of simplified workflows and streamlined platforms. Advancing research. Increasing our understanding. Publishing results.

The Illumina community is discovering more. Publishing more.



2008

- First publication describing whole-genome sequencing on human cancer¹
- Accurate human whole-genome sequencing using reversible terminator chemistry²

2009

- Demonstrates the power of second-generation transcriptome sequencing for identifying rearrangements in coding genes³
- The largest collection of samples (24) for a single cancer type to be whole-genome sequenced, documenting large sample-to-sample variability⁴

2010

- Next-generation sequencing technology provides new insights into the mechanisms of cancer progression and a greater understanding of diagnosis and treatment options⁵⁻⁷

2011

- Discovery of causative gene mutations for a rare skin cancer condition⁸

Transforming diagnostics.

New technologies. New discoveries. New hope. With innovation, insight, and commitment, the Illumina community is leading the way toward a brighter future in cancer diagnostics, therapy, and personalized treatment.

- New developments provide hope for earlier detection and better prognoses
- Novel biomarkers may lead to future treatments tailored to an individual's genetic disposition
- Individual Genome Sequencing services provide genetic information that will facilitate clinical decision making in cancer and medicine



Learn more about Illumina at
www.illumina.com/cancer

Comprehensive cancer research portfolio.



Next-Gen
Sequencing



Next-Gen
Genotyping



Sequencing + Arrays



Multiplexed
Analysis



Real-Time
PCR

Find Structural Variation

CNV Screening	■	+	+		•
CNV Discovery	■	+	+		

Detect Chromosomal Rearrangements

Breakpoint Mapping	■		■		
Insertions, Deletions, and Translocations	■	+	+	+	•

Characterize Epigenetic Changes

DNA Methylation Biomarker Panels		•	•	+	•
DNA Methylation Discovery	■		■		
ChIP-Sequencing (DNA-Protein Binding)	•		•		
Changes in Transcription Factor and Histone Binding	•		•		

Identify Variants in Gene Regions

Whole-Genome Genotyping	■	+	+		
Custom/Focused Genotyping	+	+	+	+	•
SNP Discovery	■		■		
Whole-Genome Resequencing	■		■		
Exome Resequencing	■		■		
Custom Targeted Resequencing	■		■		
Custom Amplicon Resequencing	■		■		

Profile Gene Expression

Whole-Genome Expression	+	+	+		
Focused Gene Expression					•
MicroRNA and Small RNA Profiling	+		+		•
MicroRNA and Small RNA Discovery	+		+		

- Illumina-supported intact samples
- Illumina-supported intact and degraded (FFPE) samples
- Customer-demonstrated intact and degraded (FFPE) samples

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Genome-Wide DNA Analysis BeadChips

Illumina has created a comprehensive portfolio of DNA Analysis tools by deploying industry-leading content on multi-sample Infinium® HD BeadChips. Unmatched power provides researchers the fastest path to discoveries and publication.

Infinium HD Beadchip Highlights

- **Proven Content:** Publish with confidence using a foundation of well-validated assays and markers
- **Powerful Cytogenetics:** Get high-resolution analysis with dense and uniform marker spacing with minimal gaps
- **High Density:** Assay nearly 1.2 million loci per sample
- **Multi-Sample Format:** Increase sample throughput to finish projects faster
- **Low Sample Input:** Interrogate limited sample sources, down to 200 ng of DNA per sample

Comprehensive Analysis Platform

Illumina is a leader in the field of genetic analysis with innovative tools for DNA analysis, RNA analysis, and high-throughput sequencing. With the newest generation of high-density Infinium HD products, Illumina continues to provide the most comprehensive and powerful family of DNA Analysis BeadChips, taking genotyping and copy number variation (CNV) analysis to the next level.

Infinium HD technology expands the limits of density to provide industry-leading multiplexing in multi-sample formats, while maintaining the high data quality and simple assay workflow common to all Illumina products. Furthermore, Infinium HD BeadChips have low DNA input requirements, expanding the range of sample sources that can be used for a study.

The Infinium HD products include the HumanCytoSNP-12, Human660W-Quad, Human1M-Duo, and HumanOmni1-Quad BeadChips (Figure 1). This family of Illumina BeadChips provides a broad spectrum of whole-genome DNA Analysis products to support a variety of experimental designs. Researchers have the flexibility to use panels of 300,000 to nearly 1,200,000 markers per sample, depending on their study goals. All of these BeadChips provide powerful and integrated genome-wide SNP genotyping and structural variant detection. The 12-sample HumanCytoSNP-12 is a streamlined whole-genome scanning panel for high sample throughput analysis of genetic and structural variation, including cytogenetic abnormalities. The powerful Human660W-Quad BeadChip has an ideal combination of high-coverage genome-wide SNP and CNV markers in a high-throughput format. The two-sample Human1M-Duo BeadChip provides comprehensive access to the genome with nearly 1.2 million markers covering genome-wide SNPs, CNV-targeted markers, and high-value functional regions. The four-sample HumanOmni1-Quad offers the best combination of power and throughput, featuring over one million strategically selected markers that deliver dense genome-wide coverage and extensive disease-associated content, including data from the 1000 Genomes Project. The unparalleled content and assay technology of Infinium HD BeadChips provide the fastest path to discoveries and publication.

Figure 1: Infinium HD Beadchips



Infinium HD BeadChips provide a broad range of powerful content options in high-throughput formats for processing two, four, or 12 samples simultaneously.

Powerful Markers

Genome-wide association studies (GWAS) rely on genotyping SNPs near a disease locus to identify genetic links to disease. As highlighted in a study from University of Michigan researchers comparing different array platforms, Illumina's marker selection strategy is demonstrably better for GWAS studies¹. Infinium BeadChips offer benefits in terms of several critical parameters that together contribute to the statistical power in an experiment: genomic coverage, array efficiency, genic coverage, call rate, and call accuracy².

The power to detect an association depends on the linkage disequilibrium (r^2) between the genotyped marker and the adjacent disease-causing SNP. A high r^2 between two SNPs indicates that the two SNPs can act as good proxies (tag SNPs) for each other³. Because the Infinium HD Assay chemistry—like the Infinium II Assay—affords flexible marker selection, Illumina scientists are able to rationally select loci that provide the highest information content, while using fewer SNPs. Illumina has taken advantage of this flexibility by selecting powerful tag SNPs and other high-value regions for markers. A result of this strategy is that the ~300,000 markers on the HumanCytoSNP-12 provide nearly the same genomic coverage in the Caucasian (CEU) population as a competing 924,000-marker array.

Compared to microarrays with randomly selected SNP content, Illumina's DNA Analysis BeadChips offer the industry's highest statistical power per sample by reducing the correction factor for multiple testing by almost 40%. Higher power means fewer samples are needed to identify significant genetic variations. Studies can be completed faster and more economically to support rapid publication in top-tier journals (for examples, browse customer citations at www.illumina.com/publications).

Comprehensive Coverage

Illumina DNA Analysis BeadChips provide optimized panels for surveying genetic variants^{1,4}. All genome-wide Infinium DNA Analysis products start with a broad set of tag SNPs and other valuable SNPs from the International HapMap Project and NCBI's dbSNP to provide high genomic coverage and uniformity across the genome. All genome-wide DNA Analysis products also include a set of additional CNV-targeted markers designed to increase coverage of regions underrepresented by tag SNPs.

In the Illumina portfolio, individual BeadChips offer slightly different content and numbers of markers to provide flexible options for using the optimal content panel in any study design (Table 1).

HumanCytoSNP-12 DNA Analysis BeadChip Content

The HumanCytoSNP-12 BeadChip represents the most efficiency-optimized DNA Analysis content selection strategy. It includes a complete panel of genome-wide tag SNPs and additional markers targeting all regions of known cytogenetic importance.

Illumina scientists employed 200,000 "best of the best" SNPs that have the highest tagging power. This content maintains the exceptional genome-wide SNP coverage that Illumina is known for (70% in CEU at $r^2 > 0.8$) because of the efficient marker design strategy². At the same time, a set of 220,000 markers provides extra utility for cytogenetic analysis. This includes dense coverage of ~250 genomic regions commonly studied in cytogenetics labs and targeted coverage in additional genes, subtelomeric regions, pericentromeric regions, and sex chromosomes⁵.

Furthermore, the HumanCytoSNP-12 takes advantage of the industry's first 12-sample whole-genome BeadChip and Illumina's high-density array technology to provide the highest throughput and most cost-effective BeadChip.

Human660W-Quad DNA Analysis BeadChip Content

The Human660W-Quad BeadChip offers comprehensive genomic coverage across many populations and the majority of known variation in regions of the genome based on HapMap data.

The Human660W-Quad BeadChip builds on the content of the highly successful HumanHap550 BeadChip. The broad, evenly spaced whole-genome marker set provides high genomic coverage for powerful GWAS. In addition, the Human660W-Quad BeadChip provides 87%, 85%, and 56% coverage of CEU, CHB+JPT, and YRI populations at $r^2 > 0.8$ (Figure 2).

For equally powerful CNV and cytogenetic analysis, this dense backbone content is combined with an additional ~100,000 markers that target observed common CNVs.

The entire panel of 657,000 markers provides exceptional genomic coverage and identification of known and novel structural variants, combined with an efficient multi-sample format.

Human1M-Duo DNA Analysis BeadChip Content

With nearly 1.2 million markers per sample, the Human1M-Duo provides a powerful combination of quality, coverage, and throughput. The comprehensive set of markers on the Human1M-Duo BeadChip provides access to dense genome-wide tag SNP coverage as well as additional content targeted to high-value genomic regions of interest. Other probes are located in SNP deserts to fill in gaps.

The uniform genome-wide coverage results in a median spacing between markers of 1.5 kb (mean = 2.4 kb) and few large gaps for high-resolution CNV identification and cytogenetics analysis. Ensuring no regions are skipped, the 90th percentile largest gap between SNPs on the Human1M-Duo BeadChip is 6 kb. The result of this comprehensive design strategy is 95%, 93%, and 76% coverage of CEU, CHB+JPT, and YRI populations at $r^2 > 0.8$.

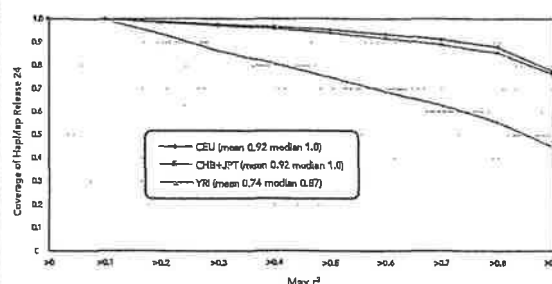
In addition to the broad coverage crucial for successful whole-genome association studies, the Human1M-Duo BeadChip targets other high-value content. Gene-centric markers selected in and around genes target both synonymous and non-synonymous SNPs to increase genic coverage. In addition, more than 10,000 markers are included for the major histocompatibility complex (MHC) region, which contains a high density of genes often associated with autoimmune and infectious diseases.

The BeadChip also features ~60,000 CNV-targeted markers, developed in collaboration with deCODE Genetics, for regions likely to contain undiscovered CNV. Novel CNV-specific probes and the dense uniform genome-wide SNP coverage support unbiased discovery and analysis of copy number polymorphisms.

HumanOmni1-Quad DNA Analysis BeadChip Content

The HumanOmni1-Quad BeadChip provides an unparalleled, extensive view of the genome, in a highthroughput, cost-effective format. A complete optimization of the BeadChip design increases the available complexity, allowing nearly five million markers to be assayed across four different samples in parallel, while reducing the amount of required DNA to 200 ng. Each BeadChip features over one million

Figure 2: Human660W-Quad Genomic Coverage



The Human660W-Quad BeadChip content covers the majority of common variation in three distinct populations. Graphs are estimated, based on the HapMap release 24 data set of > 2.3 million common SNPs.

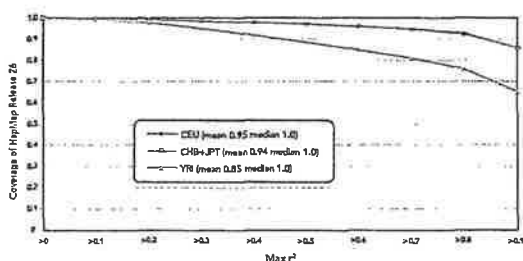
available assays per sample, containing carefully selected content that delivers dense coverage of the human genome and targets regions known to play a role in human disease. This comprehensive collection of genomic markers offers the best combination of power, price and throughput available for genome-wide association studies.

With recently released data from all three HapMap phases, intelligent tag SNP selection has been optimized to maintain comprehensive genomic coverage, while reducing SNP redundancy. This has enabled the inclusion of additional content carefully chosen to target high-value regions of the genome, such as the MHC region and new coding variants identified by the 1000 Genomes Project. The redesigned SNP selection strategy has maintained high genomic coverage rates of 93%, 92%, and 76% at $r^2 > 0.8$ for the CEU, CHB+JPT, and YRI populations, respectively (Figure 3). High density markers with a median spacing of 1.5 kb and the fewest number of large gaps for any BeadChip ensure the highest level of resolution for CNV identification in the industry.

The HumanOmni1-Quad is the only BeadChip to include cutting-edge content derived from the 1000 Genomes Project. This large international effort is dramatically increasing the information we have about genetic variation across human populations⁶. Already, the project has uncovered millions of rare and novel SNPs that will drive the next generation of microarrays. For the HumanOmni1-Quad, SNPs selected from the 1000 Genomes Project focus on regions already identified in GWAS to be associated with human disease. This content includes ~18,000 SNPs targeting four 1Mb regions known to be associated to three or more human diseases; over 50,000 SNPs predicted to be non-synonymous; 62,000 SNPs covering an additional 100 intervals surrounding published peak markers from the NHGRI GWAS database; and the remaining 950 top single-marker associated SNPs from the GWAS database.

With high-throughput processing, comprehensive genomic coverage and the ability to capture a vast amount of genetic variation, the HumanOmni1-Quad BeadChip lets you make more meaningful discoveries and take the fastest path to publication.

Figure 3: HumanOmni1-Quad Genomic Coverage



The HumanOmni1-Quad BeadChip content covers the majority of HapMap common variation in three distinct populations. Graphs are based on the HapMap release 26 data set of > 2.3 million common SNPs.

Sensitive Structural Variant Detection

Dense Uniform Markers

An important goal during the design of Infinium HD content panels was the uniform distribution of SNP markers to create the best panels for detecting structural variation, including loss of heterozygosity. With the fewest large gaps across the whole genome, the HumanOmni1-Quad BeadChip is an ideal tool for CNV researchers to use for discovery and high-resolution breakpoint mapping (Figure 4).

Intelligent Targeted Content

Of course, some regions of the genome are naturally underrepresented by tag SNPs. Illumina scientists have leveraged the flexible Infinium Assay design to generate marker sets that provide the industry's best CNV detection panels.

The HumanCytoSNP-12 BeadChip is optimized to efficiently detect cytogenetic abnormalities that are the most relevant to human disease. Its content panel targets common regions shown to be important for cytogenetic analysis⁵ and a dense backbone of coverage across the remainder of the genome.

The Human660W-Quad contains a set of ~100,000 markers that are highly informative for analyzing common CNV regions. These markers were identified in a high-density screen for CNVs that occur in two or more HapMap samples, which was conducted in collaboration with The Centre for Applied Genomics at the Hospital for Sick Children in Toronto, the Wellcome Trust Sanger Institute in the United Kingdom, and Harvard Medical School/Brigham and Women's Hospital in Boston.

The Human1M-Duo features content developed in collaboration with deCODE Genetics to blanket the "unSNPable genome" with additional non-polymorphic markers⁷. This includes difficult-to-analyze regions like megasatellites and segmental duplications, which are targeted with both SNPs and non-polymorphic probes. Many of these regions have been validated with other approaches, such as TaqMan and Southern blotting, to confirm variance in copy number in several representative populations.

The HumanOmni1-Quad includes extensive high-value content focused on disease-associated regions: cSNPs, eSNPs, indels, SNPs in mRNA splice sites, miRNA binding sites, introns, promoter regions, ADME genes, disease-associated SNPs, mitochondrial DNA, AIMS, ABO blood typing SNPs, PAR, Y-chromosome, MHC region, and HLA complex. The BeadChip also provides high CNV coverage (Figure 4), featuring 5,000+ rare CNV regions in addition to all the common CNV content available on the Human660W-Quad.

CNV-targeted probes share the same rational design strategy with all SNPs. All markers on Infinium HD BeadChips have high feature redundancy, yielding low overall noise, and all markers are used for reliable and sensitive detection of changes in copy number. The consistent marker design allows all markers to be analyzed together using GenomeStudio® Software. Completely integrated genotyping and copy number studies maximize analytical efficiency⁶⁻¹⁰.

The resulting rationally designed content on Infinium HD BeadChips supports the industry's most powerful SNP genotyping and CNV identification^{8,11}.

Table 1: Comprehensive Coverage of High-Value Regions

	HUMANCytoSNP-12 v2.1	HUMAN660w-QUAD v1	HUMAN1M-DUO v3	HumanOmni1-Quad v1
Overview	Efficient coverage for cost-effective GWAS and cytogenetic screening	High genomic coverage of common SNPs and CNV regions	Genome-wide coverage and additional high-value regions	Comprehensive genome-wide coverage and additional high-value regions, including new content from 1,000 Genomes Project
Number of Markers per Sample	299,140	657,366	1,199,167	1,140,419
Number of Samples per BeadChip	12	4	2	4
DNA Input Requirement (per sample)	200 ng	200 ng	400 ng	200 ng
Scan Times per Sample (minutes) [#]	3	9	18	13
Genomic Coverage				
CEU (Mean / Median / $r^2 > 0.8$)	0.81 / 0.94 / 0.70	0.92 / 1.0 / 0.87	0.96 / 1.0 / 0.95	0.95 / 1.0 / 0.93
CHB+JPT	0.83 / 0.94 / 0.73	0.92 / 1.0 / 0.85	0.95 / 1.0 / 0.93	0.94 / 1.0 / 0.92
YRI	0.55 / 0.52 / 0.32	0.74 / 0.87 / 0.56	0.86 / 1.0 / 0.76	0.85 / 1.0 / 0.76
Minor Allele Frequency[*]				
CEU (Mean / Median)	0.22 / 0.21	0.24 / 0.23	0.20 / 0.18	0.19 / 0.17
CHB+JPT	0.21 / 0.19	0.21 / 0.20	0.18 / 0.16	0.18 / 0.15
YRI	0.21 / 0.19	0.22 / 0.21	0.20 / 0.17	0.20 / 0.18
Spacing (kb)				
(Mean / Median)	9.7 / 6.2	4.4 / 2.3	2.4 / 1.5	2.4 / 1.2
90th %ile Largest Gap	18.7	10.6	6.0	6.4
Marker Categories				
Markers Within 10 kb of a RefSeq Gene	148,987	332,756	672,002	618,959
Non-Synonymous SNPs [§]	2,420	10,051	21,877	32,110
MHC [†] / ADME [‡] / Indel SNPs	760 / 2,388 / 0	3,177 / 8,440 / 0	10,415 / 20,493 / 483	19,081 / 22,429 / 459
Sex Chromosome (X / Y / PAR Loci)	15,400 / 2,972 / 770	16,509 / 44 / 15	45,591 / 4,637 / 979	27,493 / 2,322 / 1,157
Mitochondrial SNPs	0	135	138	27

[#] Scan times are approximations based on the iScan platform

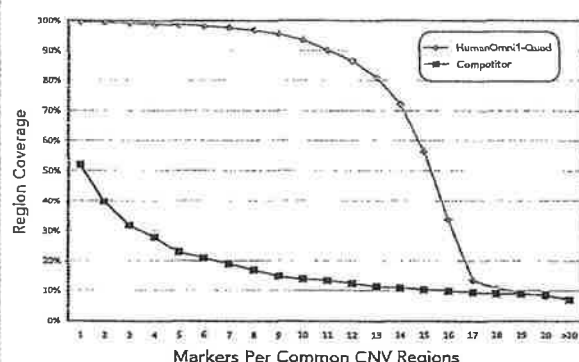
^{*}Based on HapMap rel 24 for HumanCytoSNP-12, Human660W-Quad, and HumanOmni1-Quad, and rel 23 for Human1M-Duo

[§]Based on RefSeq and Ensembl databases

[†]As defined by de Bakker, 2006

[‡]Within 10 kb of 333 known ADME-related gene

Figure 4: Outstanding Coverage of Common CNVS



The intelligent marker selection used for all Illumina BeadChips results in substantially better coverage of important regions compared to greater numbers of randomly selected markers.

Custom Content Options

Illumina offers the option of adding custom-designed content to the broad genome-wide standard SNP content on the Human1M-Duo and Human660W-Quad BeadChips. The results are semi-custom Human1M-Duo+ and HumanHap550-Quad+ BeadChips. With assistance from Illumina scientists and a proprietary Assay Design Tool, researchers can include an additional panel of up to 60,800 SNPs to the powerful standard content.

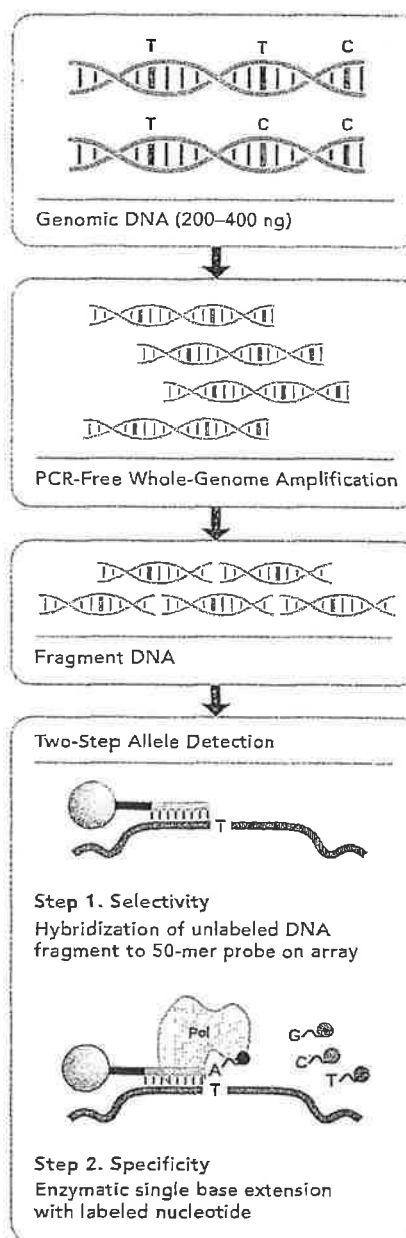
Streamlined Assay Workflow

The Infinium HD Assay can be scaled to unlimited multiplexing without compromising data quality, unlike many alternative PCR-dependent assays. The simple, streamlined workflow is common across all products, no matter how many SNPs are being interrogated. Likewise, the data acquisition process and analysis are the same.

The Infinium HD Assay protocol (Figure 5) features single-tube sample preparation and whole-genome amplification without PCR or ligation steps, significantly reducing labor and sample handling errors. After hybridizing unlabeled DNA sample to the BeadChip, two-step allele detection provides high call rates and accuracy. Selectivity and specificity are accomplished in two steps. Target hybridization to bead-bound 50-mer oligos provides high selectivity while enzymatic single-base extension provides powerful specificity. The single-base extension also incorporates a labeled nucleotide for assay readout. The staining reagent is optimized to provide a higher signal, and more balanced intensities between red and green channels. These features contribute to industry-leading accuracy, high call rates, and copy number data with lower noise.

The iScan System uses advanced optics for high-resolution detection and high-throughput readout of assay results. With this system and 12-sample BeadChips, researchers can scan each sample in three minutes (Table 1).

Figure 5: Infinium HD Assay



Multi-Sample Format

The efficient multi-sample format of Illumina BeadChips cost-effectively increases sample throughput. Reduced handling, more efficient scanning, and higher density assays contribute to higher sample throughput rates so projects are finished faster. Also, by effectively eliminating array-to-array variability, the multi-sample format is ideal for analyzing matched samples.

Low DNA Input Requirement

Infinium HD BeadChips require low quantities of input DNA, providing opportunities to use more limited sample sources (Table 1). Four- or 12-sample Infinium HD BeadChips require only 200 ng DNA per sample, and two-sample BeadChips require 400 ng DNA per sample.

High Quality Data

All of the assays on the HumanOmni1-Quad, Human1M-Duo, Human660W-Quad, and HumanCytoSNP-12 DNA Analysis BeadChips use Infinium HD chemistry. These BeadChips have undergone the same rigorous functional testing that ensures strong and reproducible performance of all Illumina products. One assessment of data quality was the analysis of a diverse panel of HapMap reference samples (Table 2). As shown in Table 2, the Infinium HD BeadChips perform extremely well, producing high call frequencies and excellent reproducibility.

Successful genome-wide association studies depend, in part, on the high call rates that Illumina DNA Analysis BeadChips exhibit. Since complex disease traits often have relatively small gene effects, potential associations may be missed if an assayed SNP, in LD with a disease SNP, has a low call rate. Data from the Infinium HD DNA Analysis BeadChips show strong reproducibility (> 99.9%) and concordance with the International HapMap Project (> 99.2%). Additionally, these BeadChips provide precise copy number metrics with low overall noise levels (Table 2), allowing reliable detection of single changes in copy number.

Internal Quality Controls

All products based on the Infinium HD Assay have several sample-dependent and sample-independent internal controls so researchers have confidence that they are producing the highest quality data. The performance of all controls can be monitored easily with the GenomeStudio Genotyping Module integrated Controls Dashboard.

Analysis Software

Illumina's GenomeStudio Data Analysis Software offers integrated genotyping and copy number tools and a graphical Genome Viewer. GenomeStudio Software has an open plug-in interface to integrate third-party applications for more downstream data analysis options. The Illumina®Connect™ program leverages this open architecture and has made numerous plug-ins available to support genotyping and copy number analysis.

iControlDB

Illumina hosts a database of genotypic and phenotypic data generated by researchers using Illumina genotyping products, which can be used to supplement controls in case-control association studies¹². Access to the thousands of controls in the free iControlDB database allow researchers to increase the power of an association study and decrease overall project costs.

Automation

As with most of Illumina's standard DNA Analysis products, an optional Laboratory Information Management System (LIMS) and robotic automation accurately and efficiently track samples to provide workflow

management and overall project management. This system, custom designed for Infinium workflows, allows labs to maximize their throughput with a completely integrated microarray solution.

Services

Illumina FastTrack Genotyping Services are available to analyze samples in a timely fashion at a reasonable cost using any Infinium DNA Analysis BeadChip. This option allows researchers to acquire high-quality data for limited studies or before purchasing their own equipment.

Summary

Illumina whole-genome DNA Analysis BeadChips are high-quality tools for SNP genotyping and analysis of structural variants. This genetic analysis platform offers a range of solutions with different numbers of markers per sample and different numbers of samples per BeadChip. All Illumina BeadChips offer the highest data quality and most complete genomic coverage in the industry. By choosing a BeadChip that matches the study design, researchers can confidently pursue the fastest path to discoveries and publication.

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14. Interpreting Infinium Assay Data for Whole-Genome Structural Variation, http://www.illumina.com/downloads/cytoanalysis_TN.pdf

Table 2: Genotyping Data Quality of DNA Analysis Beadchips Using Reference Samples

HumanCytosnp-12 BeadChip (283 DNA Samples, 15 Replicates, 56 Trios)

Genotyping Parameter	Value from Reference Samples	Product Specification	CNV Analysis Parameter	Value from Reference Samples	Expected**
Call Frequency	99.71%	> 99% average	Log R Ratio [†]	0.10	< 0.30
Reproducibility	100.00%	> 99.9%	B Allele Frequency ^{†§}	0.03	< 0.04
Mendelian Inconsistencies	0.02%	< 0.1%			
HapMap Concordance	99.77%	N/A			

Human660W-Quad BeadChip (283 DNA Samples, 15 Replicates, 58 Trios)

Genotyping Parameter	Value from Reference Samples	Product Specification	CNV Analysis Parameter	Value from Reference Samples	Expected**
Call Frequency	99.96%	> 99% average	Log R Ratio [†]	0.16	< 0.30
Reproducibility	100.00%	> 99.9%	B Allele Frequency ^{†§}	0.03	< 0.04
Mendelian Inconsistencies	0.04%	< 0.1%			
HapMap Concordance	99.76%	N/A			

Human1M-Duo BeadChip (284 DNA Samples, 15 Replicates, 58 Trios)

Genotyping Parameter	Value from Reference Samples	Product Specification	CNV Analysis Parameter	Value from Reference Samples	Expected**
Call Frequency	99.83%	> 99% average	Log R Ratio [†]	0.15	< 0.30
Reproducibility	100.00%	> 99.9%	B Allele Frequency ^{†§}	0.03	< 0.04
Mendelian Inconsistencies	0.05%	< 0.1%			
HapMap Concordance	99.63%	N/A			

HumanOmni1-Quad BeadChip (282 DNA SAMPLES, 15 REPLICATES, 56 TRIOS)

Genotyping Parameter	Value from Reference Samples	Product Specification	CNV Analysis Parameter	Value from Reference Samples	Expected**
Call Frequency	99.87%	> 99% average	Log R Ratio [†]	0.13	< 0.30
Reproducibility	100.00%	> 99.9%	B Allele Frequency ^{†§}	0.03	< 0.04
Mendelian Inconsistencies	0.02%	< 0.1%			
HapMap Concordance	99.64%	N/A			

*Based on CEU trios using loci with MAF ≥ 0.01 ; given as the frequency of markers with minor allele undertransmitted relative to the expected 50%

**Values expected for typical projects, excluding tumor samples or any samples prepared not following standard Illumina protocols

[†]Excludes sex chromosomes, mtDNA, and intensity-only loci

[§]Heterozygotes only

Data Sheet: DNA Analysis

Ordering Information

Product	BeadChips	Samples	Catalog No.
HumanCytoSNP-12 v2.1 BeadChips and Reagents	1	12	WG-320-2101
	2	24	WG-320-2102
	4	48	WG-320-2103
	24	288	WG-320-2104
	96	1,152	WG-320-2105
Human660W-Quad v1 BeadChips and Reagents	4	16	WG-311-1501
	12	48	WG-311-1502
	24	96	WG-311-1503
	96	384	WG-311-1504
Human1M-Duo v3 BeadChips and Reagents	8	16	WG-311-1105
	24	48	WG-311-1102
	48	96	WG-311-1103
	192	384	WG-311-1104
HumanOmni1-Quad v1 BeadChips and Reagents	4	16	WG-311-1110
	12	48	WG-311-1111
	24	96	WG-311-1112
	96	384	WG-311-1113

Additional Information

Visit www.illumina.com/infinium or contact us at the address below to learn more about Illumina DNA Analysis BeadChips. Related technical notes 13, 14 are available at www.illumina.com/literature.

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Diagnostic Assay Box 4 of 5

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zif 5

CFTR - Coding - Oligo Pool

1 x 600 uL

Hybridization Buffer

1 x 4.32 mL

Extension-Ligation Mix

1 x 4.8 mL

Index Primers (A501)-(A508)

1 x 192 uL

Index Primers (A701)-(A712)

1 x 128 uL

PCR Polymerase

1 x 56 uL

PCR Master Mix

1 x 2.8 mL

Library Normalization Diluent

1 x 4.8 mL

Library Division Buffer

1 x 4.5 mL

Plus Internal Control

1 x 10 uL

DX COP

DX QHS1

DX ELM3

DX A501 -

DX A701 -

DX TDP1

DX PMM2

DX LNA1

DX HT1

DX PXS

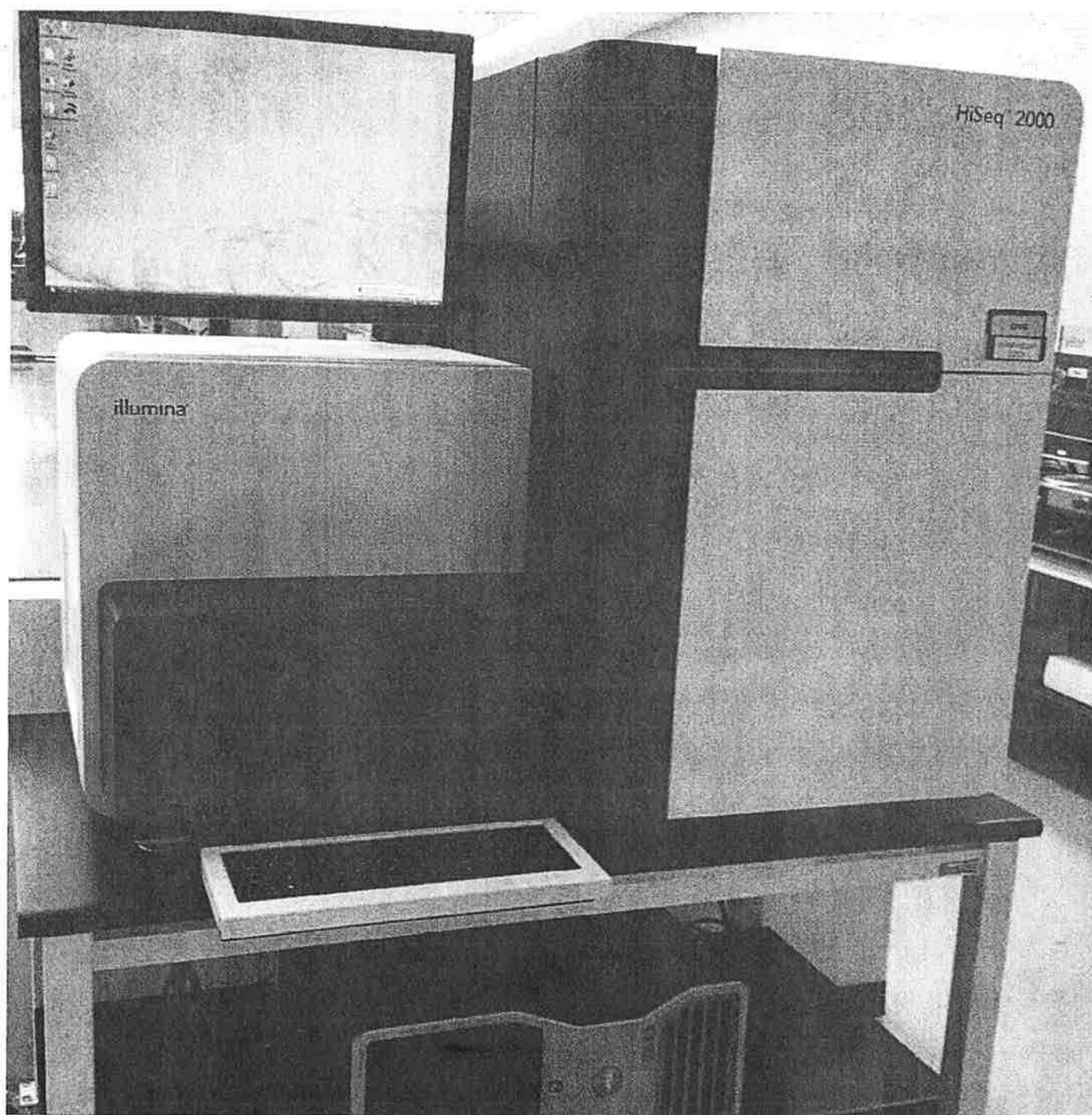
Intended Use: For use in the laboratory setting for the detection of CFTR gene mutations in human peripheral whole blood.

Product Name: MisegDx™ Cystic Fibrosis Carrier Screening Assay

Lot: PHL 1304711A

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The authors gratefully acknowledge the financial support from the National Natural Science Foundation of China (Grant No. 81073069) and the Shanghai Leading Academic Project (Grant No. Y1101.

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HiSeq™ 2000

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TruSeq™ Custom Amplicon Assay Kit
(Box 1 of 3)

REF 15025145

LOT 7005373

96 Samples

Use in Pre-Amp Area Only

2012-07-14

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San Diego, CA 92121 USA

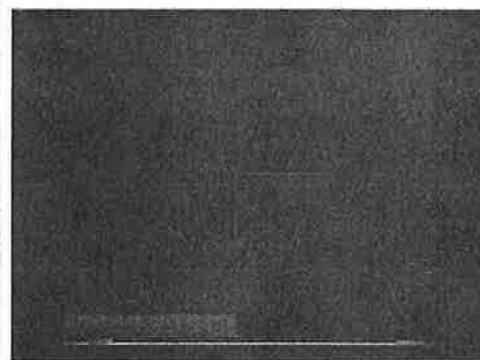


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MiSeqDx™ Instrument Reference Guide



FOR IN VITRO DIAGNOSTIC USE
FOR EXPORT ONLY

ILLUMINA PROPRIETARY
Part # 15044371 Rev. A
June 2013

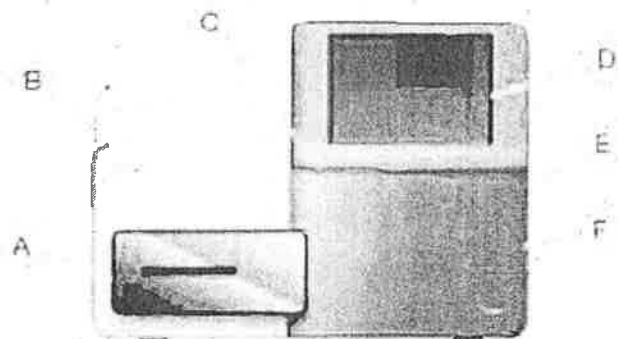
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Intended Use

The Illumina MiSeqDx instrument is a Next Generation sequencer that integrates cluster generation, sequencing and data analysis using sequencing by synthesis (SBS) chemistry. The MiSeqDx is intended for *in vitro* diagnostic use.

The MiSeqDx has the following exterior components:



- A Flow cell compartment**—Contains the flow cell stage that houses the flow cell throughout the run. Flow cell stage motors move the stage out of the enclosed optical module for flow cell loading and returns the stage when the run begins.
- B Enclosed optics module**—Contains optical components that enable imaging of the flow cell.
- C Status bar**—Uses three colors to indicate instrument status. Blue indicates that the instrument is processing, orange indicates the instrument needs attention, and green indicates that the instrument is ready to begin the next run.
- D Touch screen monitor**—Enables on-instrument configuration and run setup using the software interface.
- E External USB port**—Facilitates the transfer of files and data to the instrument computer from the touch screen monitor.
- F Reagent compartment**—Holds reagents at proper temperatures, wash solutions, and the waste bottle. A magnetic latch secures the reagent compartment door.

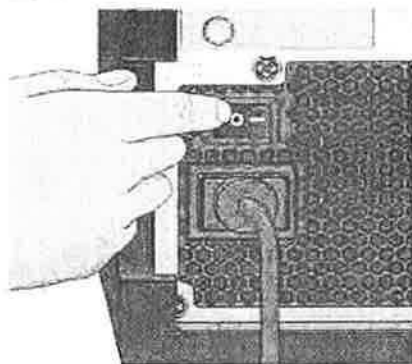
The MiSeqDx interface guides users through the run setup steps using the touch screen monitor.

**NOTE**

Illumina recommends that you leave the instrument on continuously. However, if the instrument must be turned off, follow the shutdown procedure described in *Shutting Down the Instrument* on page 74. Wait a **minimum** of 60 seconds before turning the power switch back to the ON position.

- 1 If the MiSeqDx is not already on, reach around the right side of the instrument to locate the power switch on the back panel. It is in the lower corner directly above the power cord.

Power Switch Location



- 2 Turn the power switch to the ON position. The integrated instrument computer starts.
- 3 Log in to the operating system.
Wait until the operating system has finished loading. The MiSeq Operating Software (MOS) launches and initializes the instrument automatically.
After the initialization step is complete, the Welcome screen appears.




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Illumina Clinical Services Laboratory

Overview

TruGenome Clinical Sequencing Services

For Physicians

For Patients/Guardians

About the Lab

Sign up to receive newsletters, case studies, and information on how WGS is impacting healthcare.

First

Email

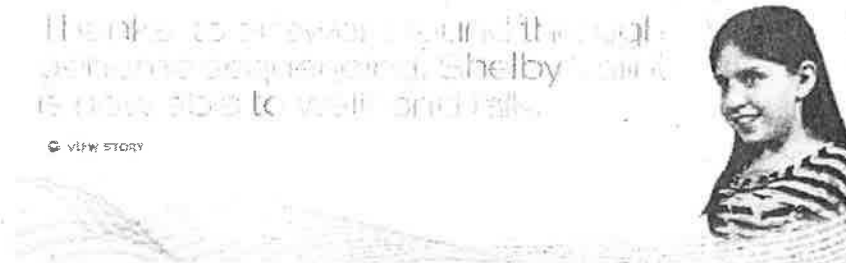
Area of Interest:

~ Please select

Lab Type:

~ Please select

[SIGN UP](#)



Genomics-based healthcare is available now for you and your patients.

We are in the beginning of a new era of using genomic information to make critical healthcare decisions. To enable you and your patients to take advantages of this transformative knowledge, Illumina Clinical Services Laboratory provides solutions to advance genomics-based healthcare.

TruGenome Clinical Sequencing tests help you both diagnose and assess your patients' risk for certain genetic diseases:

- With genome-based testing, we can deliver comprehensive answers—accurately and quickly—to your questions about genetic aberrations and rare diseases.
- You can make genetically informed decisions personalized to each patient.
- Ultimately, genome-based testing may enable us to manage health through wellness, not illness.

Service Descriptions

Currently, three TruGenome Clinical Sequencing Services are available:

- **TruGenome Undiagnosed Disease Test**
For helping find the underlying genetic cause of an undiagnosed rare genetic disease of single-gene etiology.
- **TruGenome Carrier Detection Service**
For healthy patients interested in learning about their carrier status and genetic predisposition towards adult-onset conditions.
- **TruGenome Technical Diagnostic Data**
Whole-genome sequencing in the CLIA-certified, CAP-accredited Illumina Clinical Services Laboratory for labs and physicians who will make their own clinical interpretations.

[Read more about the TruGenome Clinical Sequencing Services](#)

For Physicians

Whole-genome sequencing provides the most comprehensive genome-based testing currently available. The information gained may prove helpful in managing your patient's healthcare. In this section, you can review the process, including how to order a test, download test forms, understand how results are delivered, and find answers to frequently asked questions.

[Learn more about the genome-based testing process](#)

For Patients/Guardians

Information from your genome sequence can be used to understand how DNA changes or variations in your genome may impact your health. In this section, you'll learn more about the genome, how we read the genome, and the role of genes in inherited disease.

[Learn more about the genome](#)

About the Lab

Illumina has been providing high-quality DNA analysis services, including

DNA Sequencing Solves A Medical Mystery



Howard Jacob, Ph.D., Medical College of Wisconsin

Here's how Dr. Jacob saved a child with an undiagnosed disease.

[Watch the video](#)

In the News

- Genome sequencing for healthy individuals
- Sequence from the start

Understand Your Genome



Be a part of the movement that engages, educates, and motivates the medical community to improve overall human health.

[Get genomed](#)

next-generation sequencing (NGS), to the research community since 2001. In 2009, we established a CLIA-certified, CAP-accredited clinical laboratory, Illumina Clinical Services Laboratory, for the purpose of offering human whole-genome sequencing services to physicians and genetic counselors. All of our Clinical Laboratory Scientists are NCA-certified in molecular genetics with active California licenses as Clinical Molecular Genetic Scientists and California-approved Medical Technologists (ASCP). They have extensive training and experience with Illumina NGS technologies. In fact, the Illumina Clinical Services Laboratory was the first to generate a personal genome sequence in a clinical laboratory setting.

Learn more about us

TruSight Clinical Sequencing Services is performed in the Illumina CLIA (Clinical Laboratory Improvement Amendments)-certified and CAP (College of American Pathologists) accredited Clinical Services Laboratory. The TruSight Clinical Sequence information is generated by licensed personnel using an analytically validated process. Coverage with Laboratory Developed tests, it has not been cleared or approved by the U.S. Food and Drug Administration.

TruSight Clinical Sequence information can be analyzed to potentially aid your physician in the evaluation of a broad range of health conditions or physiological traits. You will not receive medical results, or a diagnosis, or a recommendation for treatment from Illumina. Any results arising from the analysis of your genome sequence information that might be deemed medically actionable should be confirmed using alternative testing. If you have any questions or concerns about what you learn through your genome sequence information, you should contact your physician or a genetic counselor. Currently, Illumina does not accept orders for TruSight Clinical Sequencing Services from New York.

Applications	Systems	Clinical	Services	Science	Support	Company
Sequencing	HiSeq Systems	Molecular Diagnostics	Genotype Network	Publications	Documentation	Genetics
Genotyping	Genome Analyzer IIx	Illumina Clinical Services Laboratory	FastTrack Service	Base calling	Downloads	Control UK
SNP Genotyping & CNV Analysis	HiSeq		OSPro	Microbiology	Product literature	Events
Gene Regulation & Epigenetic Analysis	HiSeq2500	Translational Genomics	Core Labs	Community	Software	Academy
Gene Expression Analysis	HiSeq	Clinical Informatics	Service Partnerships	Workflow	BaseSpace	Newsroom
Real-Time PCR	Real-Time PCR Systems		Illumina Financial Solutions		Tools	Investor Relations
Cytogenomics	Software		Illumina Connect		Human Studies	Privacy
Assemblomics	BaseSpace				Assay Design Tool	Logos
Target Genomics					Product Files	Education
Forensic Genomics					Base Call File (BCF) Support	Transparency in Supply Chain
Systems Usage					Customer Service	Method Illumina
Workflow Genomics					Training	

Innovative technologies

At Illumina, our goal is to apply innovative technologies to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. It is mission critical for us to deliver innovative, flexible, and scalable solutions to meet the needs of our customers. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and providing the highest level of quality, we strive to meet this challenge. Illumina's next-generation sequencing and array technologies are leading groundbreaking advancements in life science research, translational and consumer genomics, and molecular diagnostics.

Exhibit 206





Print Page Close Window

Verinata Health's verifi® Prenatal Test Available through the California Prenatal Screening Program

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Nov. 1, 2013-- Illumina, Inc. (NASDAQ:ILMN) today announced that the verifi® prenatal test,¹ offered by Verinata Health, an Illumina company, will be available to pregnant women in California through the state's Prenatal Screening Program. The availability of the verifi® prenatal test represents a major advance in prenatal screening, providing pregnant women with genetic information about their babies without the risk associated with invasive testing such as amniocentesis or chorionic villus sampling (CVS).

Beginning today, all pregnant women in California at increased risk of carrying a fetus with trisomy 21 (Down syndrome) or trisomy 18 (Edwards syndrome), or who have had an ultrasound showing a large nuchal translucency, will have the option of receiving a non-invasive prenatal test.

"As a designated prenatal diagnosis center, we evaluated all of the different non-invasive prenatal tests, and selected the verifi® prenatal test based on the fact it provides the fastest turnaround time at three to six days, the lowest test failure rate at less than one percent, and an exceptionally responsive staff," said Dr. Art Karimi, Director of the Institute of Prenatal Diagnosis and Reproductive Genetics.

Women screening positive who desire a non-invasive prenatal test will be referred to a designated state-approved Prenatal Diagnostic Center, many of whom have elected to offer the verifi® prenatal test for their patients. The California Prenatal Screening Program screens nearly 400,000 women annually and is the largest prenatal screening program in the world.

"California is the first state to prioritize broad non-invasive prenatal testing as a secondary screening option for high-risk pregnant women," said Vance Vanier, M.D., Vice President of Global Commercial Operations for Verinata. "We applaud the state of California for their leadership through this comprehensive Prenatal Screening Program and we are pleased to bring reliable results from the verifi® prenatal test to women throughout the state."

The California Prenatal Screening Program is conducted through the state of California Genetic Disease Screening Program. The voluntary Prenatal Screening Program was established to provide pregnant women with improved screening for genetic disorders. California offers the only comprehensive prenatal screening program that includes follow-up for all non-negative test results, non-invasive prenatal testing and/or confirmatory testing through either amniocentesis or CVS, when indicated. In cases where a genetic disorder is detected prenatally, managing the high-risk pregnancy and ensuring delivery in a hospital with a Neonatal Intensive Care Unit with the appropriate level of care provides optimal patient outcomes for these families.

About Verinata Health

Verinata (www.verinata.com), a wholly-owned subsidiary of Illumina, Inc., is driven by a sole, extraordinary purpose – maternal and fetal health. Our initial focus is to develop and offer non-invasive tests for early identification of fetal chromosomal abnormalities using our proprietary technologies. We aim to reduce the anxiety associated with today's multi-step process, the unacceptable false-positive rates, the non-specific and sometimes confusing results of current prenatal screening methods, as well as the risk of current invasive procedures. We support national guidelines and the recent American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine Committee Opinion that recommend cell-free DNA

ILLUM-1807

prenatal testing as one option for use as a primary or secondary screening test in women at increased risk of aneuploidy. We believe women who desire such testing should be offered a single blood draw test with a definitive result. The veriFi® prenatal test is available through a physician.

About Illumina

Illumina (www.illumina.com) is a leading developer, manufacturer, and marketer of life science tools and integrated systems for the analysis of genetic variation and function. We provide innovative sequencing and array-based solutions for genotyping, copy number variation analysis, methylation studies, gene expression profiling, and low-multiplex analysis of DNA, RNA, and protein. We also provide tools and services that are fueling advances in consumer genomics and diagnostics. Our technology and products accelerate genetic analysis research and its application, paving the way for molecular medicine and ultimately transforming healthcare.

Forward-Looking Statements

This release may contain forward looking statements that involve risks and uncertainties. Important factors that could cause actual results to differ materially from those in any forward-looking statements are detailed in our filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. We do not intend to update any forward-looking statements after the date of this release.

¹ The veriFi® prenatal test is a non-invasive blood test that analyzes DNA found in a pregnant woman's blood to detect chromosome abnormalities, including Down syndrome (trisomy 21 or T21), Edwards syndrome (trisomy 18 or T18), Patau syndrome (trisomy 13 or T13) and sex chromosome abnormalities, and can be used as early as 10 weeks of pregnancy.

Source: Illumina, Inc.

Illumina, Inc.

Investors:

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858-255-5243
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or

Media:

Jennifer Temple
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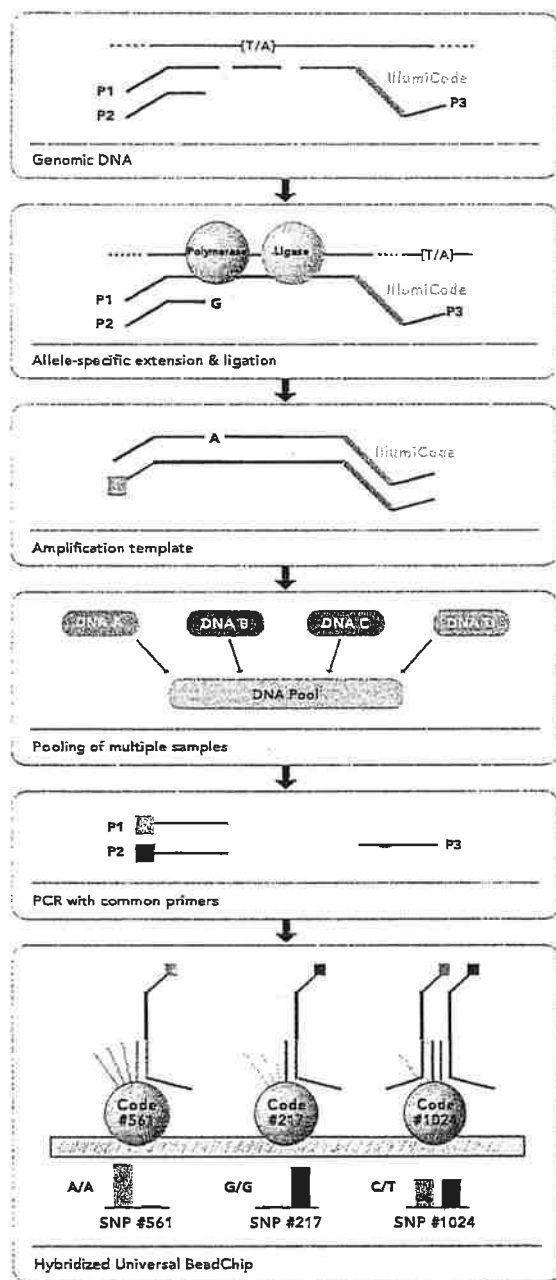
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Exhibit 214

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Figure2: Goldengate Indexing Assay Workflow



In the GoldenGate Indexing assay, a unique set of IllumiCodes is used to identify each sample, allowing multiple samples to be pooled prior to amplification. This, along with automation capabilities, greatly increases the assay throughput.

Illumina's integrated LIMS delivers state-of-the-art management and tracking to ensure the highest quality data, efficient data acquisition, and significant savings in time and lab resources. As a ready-to-use solution, Illumina LIMS includes the server hardware and software needed to accurately manage and enforce assay workflow. Illumina LIMS provides the excellent project management capabilities needed to effectively manage samples from receipt through analysis.

Positive sample tracking by Illumina LIMS is achieved by direct control of the automated liquid handling robots, ensuring samples are automatically processed and queued to the proper step and eliminating error due to manual mishandling. LIMS tracks time-stamped lab transactions with associated user information by offering user authentication either through Illumina LIMS or through existing Windows password authentication. In addition, LIMS uses a barcode system for accurate sample identification in downstream analysis. Illumina provides software updates to accommodate new product formats and workflows, saving the time and cost of in-house software development. By managing time-consuming and error-prone sample/data handling from beginning to end, the LIMS environment greatly increases confidence and efficiency in genotyping studies.

Reliable Analysis

GoldenGate Indexing Assay results can be analyzed in the genotyping module of GenomeStudio™ data analysis software. This module recognizes each IllumiCode and displays individual genotyping data for the pooled samples. In addition, GenomeStudio software features the ability to normalize raw data and perform clustering and automated genotyping calling.

Data Quality

GoldenGate Indexing Assays produce the same high-quality data as the original GoldenGate Assay. This ensures that important SNPs are captured and a high call accuracy is achieved (Table 1).

Summary

GoldenGate Indexing provides a fully automated, affordable assay for high-throughput low- to mid-plex genotype screening. Using a proven assay, researchers can now screen thousands of samples in just a few days, while still obtaining the high-quality data they require.

Additional Information

To learn how you can access the power of the GoldenGate Indexing Assay, visit www.illumina.com or contact us at the address below.

Figure 1: Specifications for the Goldengate Indexing Assay

Parameter	Specification
Average Call Rate	> 99%
Reproducibility	> 99.9%
Mendelian Inconsistencies	< 0.1%

Data Sheet: SNP Genotyping

Ordering Information

Product	Plexity	No. of Samples Indexed	No. of Samples Processed per Kit	Catalog No.
GoldenGate Indexing Assay Kit, Custom	96	16	768	GT-222-1003
	192	8	768	GT-222-1004
	384	4	768	GT-222-1005

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Illumina, IlluminaDx, Solexa, Making Sense Out of Life, Oligator, Sentrix, GoldenGate, GoldenGate Indexing, DASL, BeadArray, Array of Arrays, Infinium, BeadXpress, VeraCode, IntelliHyb, iSelect, CSeq, GenomeStudio, Genetic Energy, HiSeq, and HiScan are registered trademarks or trademarks of Illumina, Inc. All other brands and names contained herein are the property of their respective owners. Pub. No. 370-2009-009 Current as of 29 July 2010

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FGED SOCIETY

Minimum Information About a Microarray Experiment - MIAME

MIAME describes the **Minimum Information About a Microarray Experiment** that is needed to enable the interpretation of the results of the experiment unambiguously and potentially to reproduce the experiment. [Brazma et al., Nature Genetics]

The six most critical elements contributing towards MIAME are:

1. The raw data for each hybridisation (e.g., CEL or GPR files)
2. The final processed (normalised) data for the set of hybridisations in the experiment (study) (e.g., the gene expression data matrix used to draw the conclusions from the study)
3. The essential sample annotation including experimental factors and their values (e.g., compound and dose in a dose response experiment)
4. The experimental design including sample data relationships (e.g., which raw data file relates to which sample, which hybridisations are technical, which are biological replicates)
5. Sufficient annotation of the array (e.g., gene identifiers, genomic coordinates, probe oligonucleotide sequences or reference commercial array catalog number)
6. The essential laboratory and data processing protocols (e.g., what normalisation method has been used to obtain the final processed data)

For more details, see [MIAME 2.0](#).

MIAME does not specify a particular format, however, obviously the data are more usable, if it is encoded in a way that the essential information specified by MIAME can be accessed easily. FGED recommends the use of [MAGE-TAB](#) format, which is based on spreadsheets, or [MAGE-ML](#).

MIAME also does not specify any particular terminology, however for automated data exchange the use of standard controlled vocabularies and ontologies are desirable. FGED recommends the use of [MGED Ontology](#) for the description of the key experimental concepts, and where possible ontologies developed by the respective community for describing terms such as anatomy, disease, chemical compounds etc (see [OBO page](#) for more detail).

MIAME In Practice

The public repositories [ArrayExpress](#) at the [EBI \(UK\)](#), [GEO](#) at [NCBI \(US\)](#) and [CIBEX](#) at [DDBJ \(Japan\)](#) are designed to accept, hold and distribute MIAME compliant microarray data.

There is a number of [software tools](#) supporting MIAME requirements under development.

Open letter to the scientific journals about submitting MIAME compliant data [[RTF 14kb](#)] [[HTML 12kb](#)].

These [journals](#) require MIAME compliant data as a condition for publishing microarray based papers.

ArrayExpress service to journals [[PDF 508kb](#)].

MIAME extensions or related activities

- [MIBBI Project](#)
- MIAME [CGH checklist](#) [[DOC 72kb](#)] [[PDF 61kb](#)]
- MIAME [ChIP-on-chip checklist](#) [[DOC 92kb](#)] [[PDF 64kb](#)]
- MIAME proposal for random arrays [[DOC 66kb](#)] [[PDF 141kb](#)]
- [MIAME/Tox and MIAME/Env](#)
- [MIAME/Plant Whitepaper](#).

ILLUM-0859

A MIAME plant specification white paper has been produced and submitted to Plant Methods. [[PDF 51kb](#)] [[Commentary PDF 25kb](#)] [[PPT 23kb](#)]

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ILLUM-0860

As a microarray manufacturer Illumina fully appreciates the importance of MIAME as a standard necessary for meaningful interpretation and verification of microarray experiments. Our goal is to become a MIAME compliant platform when we release our gene expression related products. Therefore, I created this document to introduce the MIAME workgroup to some concepts which we think can extend the current version of the standard and enable compliance by our customers. I include a description of the Illumina array, and I would like to seek from your workgroup comments of whether they consider such description to be MIAME compliant.

Terms Needed in the Description of the Illumina Microarray Platform

- **Random Array** – this concept implies that features assemble at random locations on each physical array manufactured. In terms of changes to the Array Description part of MIAME, it would require an additional array property – ‘Array Geometry’. Describing array geometry as Random will allow us to introduce a Virtual Array Geometry placing all features present in the array onto a fixed virtual rectangular grid which makes it analogous to an ordered array. This will spare our customers the need to submit array description data with every physical array they use (it is impossible to reproduce feature locations so it does not affect verification of experiments ability). Also, virtual arrays can be helpful in describing flow cytometry gene expression data.
- **Universal Array** – this concept is not unique to Illumina and implies that probes on the array are used indirectly as address readout reporters rather than direct hybridization target quantifiers. This notion can help to create a placeholder for additional sequence information required to interpret microarray data. In case of Illumina we refer to address reporters as IllumiCode capture sequences.
- **Generalized Reporter** – this concept allows characterization of various parts of the sequence generated on the array. In particular, we propose to split reporter sequence into hybridizing part and auxiliary part. In figure 1a below, the reporter’s hybridizing sequence coincides with the gene specific portion while the auxiliary sequence functions as an IllumiCode capture sequence. Another possible function for the auxiliary sequence is to provide padding between the substrate and the gene specific sequence.

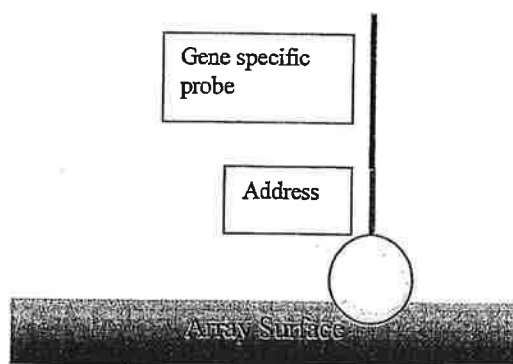


Figure 1.a

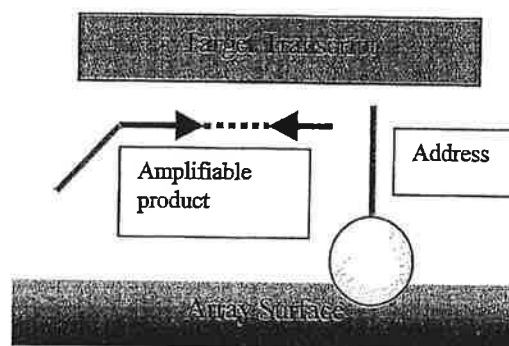


Figure 1.b

Figure 1b represents a typical universal array. In this case the sequence hybridizing to the gene specific part is not attached to the array. The reporter sequence does not have an auxiliary part, however, it serves as IllumiCode capture sequences. This could be described through an additional reporter sequence property - 'hybridization type'. It would be included in the experiment description part of MIAME. Illumina plans to release probe sequence information for gene specific portions, however, for intellectual property considerations we cannot release sequences for our IllumiCode capture sequences.

- Probe orientation – As a minor addition, we think MIAME should add additional reporter sequence property describing orientation (3' outward or inward) of probes with respect to the array surface.

To summarize these concepts here is the proposed content of Illumina's array description: Blue font represents additions either new to the current MIAME content or having new interpretation.

1. Array related information

Array Design Name= IlluminaTest

Platform Type= DNA Oligonucleotide

Surface and Coating Specification= silica beads, diameter=3 μ m.

Physical Dimension= hexagon, diameter=1.5mm

Array Geometry= Random (means that locations described below are virtual)

Number of Features on the Array= Number of distinct feature types (number of replicates per distinct feature is random)

Availability= provided by Illumina Inc.

2. (a) For each reporter type

Reporter Type = synthetic DNA oligonucleotide

Number of strands = 1

(b) For each reporter type

Identifier = illumina's unique identifier

Hybridization type = Universal or Specific

Auxiliary sequence function = (None, padding, address, etc.)

Auxiliary sequence position = proximal to surface (if exists)

Auxiliary sequence length= sequence length if exists, 0 otherwise
Specific sequence=AGCT... (gene specific portion of the sequence if exists)
Sequence orientation= 5' proximal to surface

3. (a) For each feature type
 Dimension = diameter 3 μ m
 (b) For each feature
 Reporter identifier
 Location on the virtual array.
4. For each composite sequence
 List of reporters
 Reference sequence
 Gene name
5. Control Elements
 Position of the feature on virtual array
 Control type
 Control qualifier

In the Experiment Description section we propose to introduce the following descriptor:

For each universal reporter:

 Specific sequence
 Element of the array expected to hybridize to it

In terms of raw data, Illumina will provide customers with gene expression data tables which would list for all features described in array descriptor:

- Feature Identifier
- Average Intensity
- Number of Beads
- Bead to Bead Standard Deviation
- Detection p-value.

In addition, customers will have raw images, so they will be able to examine images for scratches, intensity gradients, etc. We will make our extraction algorithms and normalization routines public.

Exhibit 215

$\Delta \pi$ EXHIBIT <u>215</u>	
Deponent <u>Rossemuto</u>	
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1-215

Illuminotes

April 2011



Product News

New TruSeq™ Enrichment Demo Kits

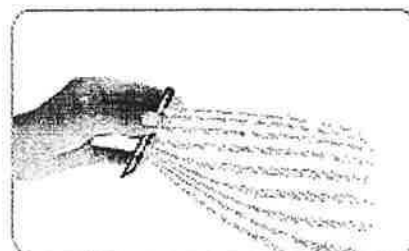
New demo kits allow customers to try TruSeq Exome Enrichment on their own samples. Limited to one per laboratory, the kit provides TruSeq DNA Sample Preparation and TruSeq Exome Enrichment reagents for up to 24 samples. Contact your local Account Manager or Illumina customer support for more information.

Final Order Date for RatRef-12

The final order date for RatRef-12 BeadChips is May 31, 2011, or while supplies last, with a final shipment date of June 30, 2011. Contact your local Account Manager or Illumina customer support for assistance in transitioning to RNA sequencing and the TruSeq RNA Sample Prep Kit for your next gene expression profiling experiment.

Final Order Date for Human660W-Quad, Human610-Quad, Human1M-Duo, Human1MDuo+, and HumanHap550-Quad+ BeadChips

The final order date for these Infinium® BeadChips is April 29, 2011, or while supplies last, with a final shipment date of June 30, 2011. Contact your local Account Manager or Illumina customer support for assistance in transitioning to the Omni family of microarrays for GWAS projects.



Start Using RNA Sequencing

Learn how other researchers are benefiting from RNA-Seq by signing up for Illumina's three-part RNA Sequencing webinar series.

New Products

- MiSeq™ Personal Sequencing System
- Infinium DNA Restoration Solution
- TruSeq DNA Fragmentation and Size Selection Automation

Customer Satisfaction

Enhanced HiSeq™ Flow Cell QC and Manufacturing

We are continually improving and updating our processes to deliver the highest quality products. Our commitment to customer satisfaction also involves listening to your concerns and correcting product issues. This new section of Illuminotes is devoted to communicating those solutions to you in a timely fashion.

Recently, some HiSeq customers experienced issues with flow cell performance. We made modifications to our HiSeq flow cell quality control and manufacturing processes, resolving the edge-effect issues and supporting more uniform clustering. Since February 2011, all shipped HiSeq Cluster Kits have contained updated flow cells. We are continuing to replace the flow cells of impacted customers. For more

Illumina Seminar Series

Registration is open for these upcoming seminars:

Sequencing Seminars

- Berlin - May 3
- Lausanne - May 4
- Uppsala - May 11
- Copenhagen - May 12
- Brussels - May 18
- Amsterdam - May 19
- Paris - June 15
- Milan - June 16
- Barcelona - June 22
- Rome - June 23

ILLUM-0864

information, contact Illumina technical support.

IDEA Challenge Conference

Register Now for the iDEA Conference - June 14-15, 2011 San Diego, CA

The iDEA Conference will showcase innovative ideas for the visualization and analysis of Illumina datasets from around the world, highlighted by the announcement of the six iDEA Challenge award winners. Space is limited, so register today!

Product Literature

Optimize Targeted Resequencing

Maximize the efficiency of your targeted resequencing studies with the new TruSeq Exome Enrichment Kit. An updated data sheet provides details about the kit, its workflow, input requirements, and data accuracy, while a new technical note discusses how to optimize coverage for highly sensitive variant calling.

RNA-Seq Analysis Demystified

A new data sheet provides a broad overview of RNA-Seq data analysis, demystifying the tools—from Illumina and third-parties—to make your studies successful. See a comparison of microarray and RNA-Seq data in a new white paper, comparing the ability of each platform to detect and quantify differential gene expression across two well-annotated samples.

Documentation

The following new documentation is available:

- HiSeq 1000 User Guide and Quick Reference Guide
- Infinium HD DNA Restoration Protocol Instructions
- Infinium HD FFPE QC Instructions, Assay Guide, Experienced User Card, and Lab Tracking Form
- Sample Stats Report Plug-in for GenomeStudio® Software
- GC Content Polynomial Fit C# Script for GenomeStudio Software

The following documentation has been updated recently:

- HiSeq Lab Tracking Form
- cnvPartition CNV Analysis Plug-in for GenomeStudio Software
- TruSeq Small RNA Sample Preparation Guide,

- London – June 28
- Glasgow – June 29
- Birmingham – July 5
- Leeds – July 6

Illumina Regional User Group Meetings

Illumina is hosting 13 regional user group meetings in North America, providing customers with a forum to share results, receive updates on the latest applications and products, and exchange best practices to get the most from their Illumina systems.

Registration is open for the following meetings:

- April 26 - San Diego, California
- June 1 - New York, New York
- June 7 - Bethesda, Maryland
- June 9 - Boston, Massachusetts

July 2011 (specific dates TBD)

- San Francisco Bay Area, California
- Seattle, Washington
- Los Angeles, California
- St. Louis, Missouri
- Toronto, Ontario, Canada
- Houston, Texas
- Philadelphia, Pennsylvania

Upcoming Events

European Molecular Biology Laboratory (EMBL) Advanced Course-Next-Gen Sequencing Data Analysis
May 3-4
Heidelberg, Germany

International Friedreich's Ataxia Scientific Conference
May 5-7
Illkirch, France

- Leena Pelonen-Palohe
Symposium-A Global View of Disease Genetics
May 18-19

- Experienced User Card, and Lab Tracking Form
- VeraCode ADME Core Panel Guide and Lab Tracking Form

View or download PDFs of all current Illumina documentation here using your iCom login. To register for an iCom account click here.

Experimental Protocols

Protocols Provide New Application Options

Your research might benefit from experimental applications of Illumina technology. The following protocols are now available:

- Ultra-Low-Input mRNA-Seq Guide
- Directional mRNA-Seq Sample Preparation Guide
- DSN Normalization Sample Preparation Application Note

Please note that these protocols are not supported by Illumina Technical Support or Field Application scientists, and may prove challenging to even the most experienced user.

iCommunity Newsletter

March iCommunity Now Online

Learn how customers are using Illumina products to enhance their research. The March iCommunity includes articles about adaptive immune system research, autism discoveries, breast cancer diagnostics, and sheep breeding selection. Subscribe today!

Recent Publications

Jones SJ, Laskin J et al. (2010) Evolution of an adenocarcinoma in response to selection by targeted kinase inhibitors. *Genome Biol* 11: R82.

Goudie DR, D'Alessandro M et al. (2011) Multiple self-healing squamous epithelioma is caused by a disease-specific spectrum of mutations in TGFBR1. *Nat Genet* [Epub ahead of print].

Bonnefond A, Durand E et al. (2010) Molecular diagnosis of neonatal diabetes mellitus using next-generation sequencing of the whole exome. *PLoS ONE* 5: e13630.

Garday JL, Johnston JC et al. (2011) Whole-genome sequencing and social-network analysis of a

Helsinki, Finland

- European Symposium on Bio-Organic Chemistry (ESBOC)
May 20-22
Gregynog, Wales,
United Kingdom

European Society of Human Genetics (ESHG)
May 28-31
Amsterdam, the Netherlands

Attend the Illumina
Technology Workshop:
Sunday, May 29
6:00pm-8:15pm
Booth #244

- Genetic Epidemiology
May 30-June 1
Paris, France
- International Rapeseed Congress
June 5-9
Prague, Czech Republic

Copenhagenomics: Genomics
Conference on Improving
Human Health
June 9-10
Copenhagen, Denmark

- Infectious Disease Research Network (IDRN)-Microbial Community Profiling Workshop
June 20
London, United Kingdom

International Committee for Animal Recording (ICAR)
June 22-24
Bourg-en-Bresse, France

View Webinar Archives

ILLUM-0866

tuberculosis outbreak. N Engl J Med 364: 730-739.

Rosenthal AZ, Matson EG et al. (2011) RNA-seq reveals cooperative metabolic interactions between two termite-gut spirochete species in co-culture. ISME J [Epub ahead of print].

Polymenidou M, Lagier-Tourenne C et al. (2011) Long pre-mRNA depletion and RNA missplicing contribute to neuronal vulnerability from loss of TDP-43. Nat Neurosci [Epub ahead of print].

Wang W, Barnaby JY et al. (2011) Timing of plant immune responses by a central circadian regulator. Nature 470: 110-114.

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Illuminotes

June 2011



Product News

New GWAS Manifests Available

New build 37 manifests (April Release 2011) for all current Illumina standard GWAS microarrays, including the latest updates to marker names and positions, are now available. For further information, please contact Illumina technical support.

Discover, Develop, and Deploy with Illumina's Agrigenomics Toolset

Illumina systems and products support multiple agrigenomics applications to advance research and commercial efforts, including enhancing breeding programs (see our new video).

TruSeq

Sequencing Data Accuracy Comparison

A side-by-side analysis of the data quality generated using Illumina sequencing and a competing services company technology is now available. Analysis was performed using transparent, reproducible methods and publically available data sets.

Product Literature

MiSeq™ Sequencing Data Available!

Download the MiSeq poster presented at the 2011 Cold Spring Harbor Biology of Genomes Meeting and an accompanying presentation describing amplicon sequencing from FFPE samples, metagenomic sequencing, de novo sequencing, and more. An application note describing the amplicon sequencing experiments in more detail is also available.

New Products

- Infinium® HD HumanOmni2.5 and HumanOmni5 BeadChips
- TruSeq v3 Reagent Kits
- MiSeq Personal Sequencing System
- Infinium DNA Restoration Solution
- TruSeq DNA Fragmentation and Size Selection Automation

Customer Satisfaction

Product Labeling Improvements

We are enhancing the information content of our packaging and recently developed an easier to read product label format, incorporating expiration date detail and internationally recognized symbols for product information. This new labeling format now appears on TruSeq reagent kits and will soon be standard for all new Illumina products.

Documentation

The following new documentation is available:

- Version Compatibility Reference Guide for HiSeq™ Sequencing Components

Illumina Seminar Series

Registration is open for these upcoming seminars:

Sequencing Seminars

- Barcelona - June 22
- Rome - June 23
- London - June 28
- Glasgow - June 29

ILLUM0868

- TruSeq Sample Preparation Best Practices and Troubleshooting Guide
- GenomeStudio® 2011.1 Online Help (covers Framework and Methylation Module)
- Infinium LCG Assay Protocol Guide, Experienced User Cards, and Lab Tracking Form for use with HumanOmni2.5-8 BeadChip
- Infinium Multi-Use LCG Assay Protocol Guide, Experienced User Cards, and Lab Tracking Form for use with HumanOmni2.5-8 Multi-Use BeadChip
- HumanOmni2.5-8 BeadChip Product Information Sheet
- HumanOmni2.5-8 Multi-Use BeadChip Product Information Sheet

The following documentation has been updated recently:

- TruSeq DNA Sample Preparation Guide, Experienced User Cards, and Lab Tracking Forms (includes new gel-free protocol option)
- TruSeq Enrichment Guide, Experienced User Card, and Lab Tracking Form (includes new custom enrichment kit)
- CASAVA v1.8 User Guide and Quick Reference Guide
- Eco™ Real-Time PCR System User Guide
- Infinium HD HumanMethylation450 BeadChip Assay Protocol Guide, Experienced User Cards, and Lab Tracking Form (with Illumina LIMS support)

View or download PDFs of all current Illumina documentation here using your iCom login. To register for an iCom account click here.

Recent Publications

Totoki Y, Tatsuno K, et al. (2011) High-resolution characterization of a hepatocellular carcinoma genome. *Nat Gen* 43: 464-469.

Feldman AL, Dogan A, et al. (2011) Discovery of recurrent t(6;7)(p25.3;q32.3) translocations in ALK-negative anaplastic large cell lymphomas by massively parallel genomic sequencing. *Blood* 117: 915-919.

Jiao Y, Shi C, et al. (2011) DAXX/ATRX, MEN1, and mTOR Pathway Genes Are Frequently Altered in Pancreatic Neuroendocrine Tumors. *Science* 331: 1199-1203. Reviewed by Elsässer SJ, Allis CD and Lewis PW (2011) Cancer. New epigenetic drivers of cancers. *Science* 331: 1145-1146.

Shi CY, Yang H, et al. (2011) Deep sequencing of the *Camellia sinensis* transcriptome revealed candidate genes for major metabolic pathways of tea-specific compounds. *BMC Genomics* 12:131.

- Birmingham – July 5
- Leeds – July 6

Illumina Regional User Group Meetings

Illumina is hosting regional user group meetings in North America, providing customers with a forum to share results, receive updates on the latest applications and products, and exchange best practices to get the most from their Illumina systems.

Registration is open for the following meetings:

San Francisco - August 3

Boston - September 8

Dates still to be determined for the following cities:

- Seattle, Washington
- Los Angeles, California
- St. Louis, Missouri
- Toronto, Ontario, Canada
- Houston, Texas
- Philadelphia, Pennsylvania

Upcoming Events

- Infectious Disease Research Network (IDRN)-Microbial Community Profiling Workshop
June 20
London, United Kingdom

International Committee for Animal Recording (ICAR)
June 22-24
Bourg-en-Bresse, France

- Berlin Summer Meeting
June 23-25
Berlin, Germany

- JOBIM
June 28-July 1
Paris, France

ILLUM-0869

Wenping H, Yuan Z, et al. (2011) De novo transcriptome sequencing in *Salvia miltiorrhiza* to identify genes involved in the biosynthesis of active ingredients. *Genomics*. (Epub ahead of print.)

Shan L, Yang HC, et al. (2011) Influence of host gene transcription level and orientation on HIV-1 latency in a primary-cell model. *J Virol* 85: 5384-5393.

Yu H, Xie W, et al. (2011) Gains in QTL detection using an ultra-high density SNP map based on population sequencing relative to traditional RFLP/SSR markers. *PLoS One* 6: e17595.

Bomar L, Maltz M, et al. (2011) Directed culturing of microorganisms using metatranscriptomics. *MBio* 2: e00012-00011.

[View additional publications](#)

- EU Cytogenetics Conference
July 2-5
Porto, Portugal
- ICGEB DNA Tumour Virus Meeting
July 17-22
Trieste, Italy
- CeBITec Symposium
July 18-20
Bielefeld, Germany
- 50 Years of X Inactivation Research
July 20-24
Oxford, United Kingdom
- The Leena Peltonen School of Human Genetics
August 21-25
Hinxtun, United Kingdom

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Illuminotes

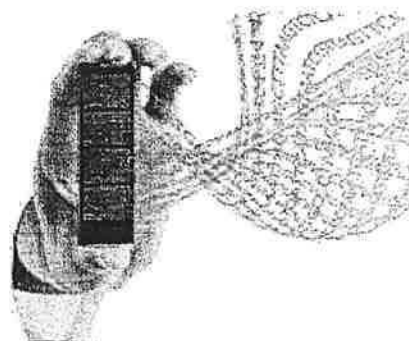
August 2011



Customer Satisfaction

Automated Filling Technologies Enhance Reagent Manufacturing

To improve product lead time and quality, Illumina is transitioning to automated filling technologies in our reagent manufacturing operation. Our new systems ensure consistent reagent fill levels within and across manufactured lots, label accuracy and proper capping.



Product News

TruSeq™ RNA and DNA Sample Prep Kits v2 Offer More Indexed Adapters

TruSeq RNA and DNA Sample Preparation Kits v2 now offer 24 indexed adapters, supporting higher levels of multiplexing and optimized fill volumes for manual and automated deployment.

LIMS Supports Infinium® HumanMethylation450 BeadChip

Illumina's state-of-the-art LIMS is now available for the HumanMethylation450 BeadChip, providing positive sample tracking, component verification, project and data management, lab workflow management, and reporting.

HumanOmni5-Quad BeadChip Now Shipping

Delivering the most comprehensive coverage of the genome, the HumanOmni5-Quad BeadChip also provides the flexibility to add up to 500K custom markers for targeted applications and population-specific studies.

Customer Input

Interested in Methylation?

We are currently assessing the level of customer interest in and capturing guidance for the design of an Infinium mouse methylation array. If you would be interested in such a product we would appreciate hearing from you.

New Products

- TruSeq Custom Enrichment Kits
- MiSeq™ Personal Sequencing System
- TruSeq DNA Fragmentation and Size Selection Automation
- GenomeStudio® Supports Polyploidy Genotyping and More

Documentation

The following new documentation is available:

- TruSeq DNA Sample Preparation v2 Guide, and Low-Throughput and High-Throughput Experienced User Cards and Lab Tracking Forms

Illumina User Group Meetings

Illumina is hosting user group meetings in North America and Europe, providing customers with a forum to share results, receive updates on the latest applications and products, and exchange best practices to get the most from their Illumina systems.

ILLUM-0871

- TruSeq RNA Sample Preparation v2 Guide, and Low-Throughput and High-Throughput Experienced User Cards and Lab Tracking Forms

The following documentation has been updated recently:

- HiScanSQ™ System User Guide and Quick Reference Guide

View or download PDFs of all current Illumina documentation here using your Illumina online account login. To register for an online account click [here](#).

Product Literature

Optimize Analysis Efficiency of Whole-Genome Genotyping

A new tech note demonstrates how to minimize sample processing time for high- and low-throughput environments.

Online Training

Online Courses Available

Two new courses have been added to the Illumina customer Online Learning Portal:

- DesignStudio™ Software
- CASAVA Software

If you need an online learning account, please contact your local account manager or Illumina customer support.

Recent Publications

Avrani S, Wurtzel O, Sharon I, Sorek R, Lindell D. (2011) Genomic island variability facilitates *Prochlorococcus* – virus coexistence. *Nature* 474:604-608.

Barchi L, Lanteri S, Portis E, Acquadro A, Valè, et al. (2011) Identification of SNP and SSR markers in eggplant using RAD tag sequencing. *BMC Genomics* 12:304-313.

Ju YS, Kim JI, Kim S, Hong D, Park H, et al. (2011) Extensive genomic and transcriptional diversity identified through massively parallel DNA and RNA sequencing of eighteen Korean individuals. *Nat Genet.* 43:745-752.

Larman HB, Zhao Z, Laserson U, Li MZ, Ciccio A, et al. (2011) Autoantigen discovery with a synthetic human peptidome. *Nat Biotechnol.* 29:535-541.

North American User Group Meetings

- * St. Louis – August 23-24
- * Boston – September 8
- * Seattle – September 13
- * Nashville – September 15
- Los Angeles – October 20
- Houston – November 8
- Philadelphia – November 10
- Toronto, Ontario, Canada – December 15

European User Group Meetings

- * Heidelberg, Germany – September 13-14
- * Copenhagen, Denmark – September 20-21
- * Nice, France – October 17-18

Agrigenomics User Group Meeting

- * St. Louis – August 25
- *Registration is open

Upcoming Events

- The Leena Peltonen School of Human Genetics
August 21-25
Hinxton, United Kingdom
- UK Next-Generation Sequencing
August 30 - September 1
Nottingham, United Kingdom
- Eucarpia Fodder Crops and Amenity Grasses Section Meeting
September 4-8
Dublin, Ireland
- Spanish Society of Biochemistry and Molecular Biology (SEBBM)
September 5-8
Barcelona, Spain
- MipTec
September 20-22
Basel, Switzerland

ILLUM-0872

Li M, Wang IX, Li Y, Bruzel A, Richards AL, et al. (2011) Widespread RNA and DNA sequence differences in the human transcriptome. *Science* 333:53-58.

Li Y, Sidore C, Kang HM, Boehnke M, Abecasis GR. (2011) Low-coverage sequencing: Implications for design of complex trait association studies. *Genome Res.* 21:940-951.

Morin RD, Mendez-Lago M, Mungall Aj, Goya R, Mungall KL, et al. (2011) Frequent mutation of histone-modifying genes in non-Hodgkin lymphoma. *Nature* [Epub ahead of print].

Toung JM, Morley M, Li M, Cheung VG. (2011) RNA-sequence analysis of human B-cells. *Genome Res.* 21:991-998.

- International Congress on Human Genetics/American Society of Human Genetics (ICHG/ASHG)
October 11-15
Montreal, Quebec, Canada
Visit Illumina at Booth #708

Attend the Illumina Technology Workshops:

Illumina Sequencing Solutions for Every Need. Every Budget. Every Lab.

Wednesday, October 12
12:45pm at the Westin Hotel

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Using Multiple Illumina Technologies for Comprehensive Genomic Analysis

Thursday, October 13
12:45pm at the Westin Hotel

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ILLUM-0873

Illuminotes

September 2011



Product News

New Tools for Epigenetics Studies

Planning an epigenetic study? Illumina offers a broad range of products for robust interrogation of multiple forms of epigenetic regulation. Learn more about our rapidly growing portfolio, including:

- Protocols and data analysis software for whole-genome bisulfite sequencing (WGBS) and reduced representation bisulfite sequencing (RRBS)
- Protocols enabling FFPE samples to be run on the Infinium HumanMethylation450 BeadChip
- Data analysis software for small RNA

Webinar

Designing TruSeq Custom Enrichment Content

Learn best practices for designing TruSeq Custom Enrichment content and obtain an in-depth review of how to modify your custom projects in GenomeStudio software.

Documentation

The following new documentation is available:

- MiSeq System Site Preparation Guide, Safety and Compliance Guide, User Guide, and Quick Reference Guide
- MiSeq Reagent Preparation Guide
- MiSeq Sample Sheet Quick Reference Guide
- Infinium HD FFPE Methylation Experienced User Cards
- Using Passive Reference Dyes for Normalization and Troubleshooting in qPCR Technical Note
- Sequencing Analysis Workflow Help
- Flicker User Guide
- Bisulfite Sequencing Analysis Software User Guide

The following documentation has been updated recently:

- Infinium HD FFPE QC Instructions and DNA Restoration Protocol

TruSeq

TruSeq Custom Enrichment Trial Kit Available

The TruSeq Custom Enrichment Kit provides a cost-effective, scalable, custom targeted sequencing solution. View the design coordinates and gene list for this in-solution capture assay. Contact your Account Manager to order a trial kit.

New Products

- MiSeq™ Personal Sequencing System
- TruSeq DNA Fragmentation and Size Selection Automation
- GenomeStudio® Software Supports Polyploidy Genotyping and More

Illumina User Group Meetings

Illumina is hosting user group meetings in North America and Europe, providing customers with a forum to share results, receive updates on the latest applications and products, and exchange best practices to get the most from their Illumina systems.

Registration is open for the following meetings:

North American User Group Meetings

ILLUM-0874

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We'd Like Your Opinion

How does Illumina rate when it comes to documentation? Complete our survey and earn a chance to win an **iPod Shuffle**.

Demonstrated Protocols

New Methylation Analysis Protocol

Your research might benefit from experimental applications of Illumina technology. The following Illumina demonstrated protocols are now available:

- Whole-Genome Bisulfite Sequencing for Methylation Analysis Guide
- Reduced Representation Bisulfite Sequencing for Methylation Analysis Guide

Please note that this protocol is not supported by Illumina Technical Support or Field Application scientists, and may prove challenging to even the most experienced user.

Recent Publications

Holbrook JD, Parker JS, et al. (2011) Deep sequencing of gastric carcinoma reveals somatic mutations relevant to personalized medicine. *J Transl Med* 9: 119.

Bass AJ, Lawrence MS, Brace LE, et al. (2011) Genomic sequencing of colorectal adenocarcinomas identifies a recurrent VTI1A-TCF7L2 fusion. *Nat Genet*. [Epub ahead of print]

Mutreja A, Kim DW, Thomson NR, et al. (2011) Evidence for several waves of global transmission in the seventh cholera pandemic. *Nature*. [Epub ahead of print]

Gracheva EO, Cordero-Morales JF, et al. (2011) Ganglion-specific splicing of TRPV1 underlies infrared sensation in vampire bats. *Nature* 476: 88-91.

Belgard TG, Marques AC, et al. (2011) A transcriptomic atlas of mouse neocortical layers. *Neuron* 71: 605-616.

Mercer TR, Neph S, et al. (2011) The human mitochondrial transcriptome. *Cell* 146: 645-658.

Jabbari A, Suarez-Farinas M, et al. (2011) Transcriptional profiling of psoriasis using RNA-Seq reveals previously unidentified differentially expressed genes. *J Invest Dermatol*. [Epub ahead of print]

Robinson T, Campino SG, et al. (2011) Drug-resistant genotypes and multi-clonality in *Plasmodium falciparum*

Los Angeles – October 20

European User Group Meetings

Nice, France – October 17-18
Cambridge, United Kingdom – October 20-21

Upcoming Events

- MipTec
September 20-22
Basel, Switzerland
 - Annual National Genome Research Network (NGFN) Meeting
September 26-28
Berlin, Germany
 - System Genetics: from man to microbe from genotype to phenotype
September 29-30
Groningen, Netherlands
 - International Symposium on Human Identification (ISHI)
October 3-6
Washington, DC
 - International Symposium on Animal Functional Genomics
October 10-12
Dublin, Ireland
 - International Congress on Human Genetics/American Society of Human Genetics (ICHG/ASHG)
October 11-15
Monteral, Quebec, Canada
Visit Illumina at Booth #708
- Attend the Illumina Technology Workshops:
- Illumina Sequencing Solutions for Every Need. Every Budget. Every Lab.*
Wednesday, October 12
12:45pm at the Westin Hotel
- Using Multiple Illumina Technologies for Comprehensive Genomic Analysis*
Thursday, October 13
12:45pm at the Westin Hotel
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- Epigenetics: from Bases to

analysed by direct genome sequencing from peripheral blood of malaria patients. PLoS One 6:e23204.

Raffan E and Semple RK (2011) Next generation sequencing--implications for clinical practice. Br Med Bull. 99: 53-71.

Pathology
October 12-14
Paris, France

- National Cancer Research
Institute (NCRI) Cancer
Conference
November 6-8
Liverpool, United Kingdom

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BaseSpace™ Takes MiSeq® Data into the Cloud

BaseSpace is a secure and customizable cloud computing environment that offers streamlined MiSeq data analysis and real-time sharing capabilities without the need for onsite computing infrastructure.

New Products

Ribo-Zero™ Gold Kit Enhances rRNA Removal

The new Ribo-Zero Gold Kit for human, mouse, or rat from Epicentre (an Illumina company) removes both cytoplasmic and mitochondrial rRNA, resulting in improved RNA-Seq results and fewer wasted reads.

CASAVA Supports Nextera™ Dual Indexing

Enhanced CASAVA 1.8.2 sequence analysis software supports Nextera dual-indexed libraries on HiSeq® systems and is now available for download.

New Products

- MiSeq System
- TruSeq™ Custom Amplicon Kit
- Nextera DNA Sample Preparation Kits
- Infinium® HumanExome BeadChips
- Infinium BovineLD BeadChip
- TruSeq DNA Fragmentation and Size Selection Automation

Product News

Discontinuation of RUO VeraCode Universal Capture and Carboxyl Beads

Effective immediately, orders for RUO-labeled VeraCode Universal Capture and Carboxyl Beads will be fulfilled with high-quality, FDA-registered General Purpose Reagent (GPR) beads. For more information contact your local Account Manager.

Final Order Date for mRNA-Seq and DGE Small RNA Sample Preparation Kits

The final order date for these sequencing sample preparation kits is December 31, 2011, with a final shipment date of February 1, 2012. Contact your local Account Manager for assistance in transitioning to the TruSeq family of sample preparation kits for

Illumina Sequencing Seminar Series

Registration is open for these upcoming seminars:

November 24 – Glasgow, United Kingdom

Illumina User Group Meetings

Illumina is hosting user group meetings in North America and Europe, providing customers with a forum to share results, receive

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sequencing projects.

Product Literature

Case Studies: HiSeq 2000 System and TruSeq Exome Enrichment Kits Empower Research

Researchers at the Oklahoma Medical Research Foundation and the Genome Technology Access Center at Washington University are using the HiSeq 2000 System and TruSeq Exome Enrichment Kits to discover mutations linked with lupus, cancer, and other diseases.

Enhanced CASAVA Offers Improved Accuracy for ELAND and Variant Calling

A new technical note describes the improved alignment and variant calling accuracy of CASAVA 1.8 sequence analysis software.

Estimating Coverage for Sequencing Applications

An updated technical note provides information on how to estimate the sequencing coverage required for an experiment.

updates on the latest applications and products, and exchange best practices to get the most from their Illumina systems.

Registration is open for the following meetings:

North American User Group Meetings

Toronto, Ontario, Canada –
December 15

Upcoming Events

- Association for Molecular Pathology (AMP)
November 17-19
Grapevine, Texas

- Australasian Biospecimen Network Association (ABNA)
November 18
Perth, Australia

- New Zealand Microbiological Society (NZMS)
November 23-25
Palmerston North,
New Zealand

- Functional Genomics & Systems Biology
November 29-December 1
Hinxton, United Kingdom

- 4th International Barcode of Life
November 30-December 3
Adelaide, Australia

- Plant & Animal Genome Conference (PAG)
January 14-18
San Diego, California

- Norwegian Biochemical Society Winter Meeting
January 19-22
Storefjell, Norway

- Advances in Genome Biology and Technology (AGBT)
February 15-18
Marco Island, Florida

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Documentation

The following new documentation is available:

- BaseSpace Help

The following documentation has been updated recently:

- Estimating Sequencing Coverage Technical Note
- Whole-Genome Bisulfite Sequencing for Methylation Analysis Guide
- Cluster Station User Guide
- Version Compatibility Reference
- TruSeq Enrichment Guide, Analysis Guide, Experienced User Card, and Lab Tracking Form

View or download PDFs of all current Illumina documentation here using your MyIllumina account login. To register for a MyIllumina account click here.

Online Training

MiSeq and TruSeq Online Courses Available

Several new courses have been added to the Illumina Customer Online Learning Portal, from Introductory Sequencing and Getting Started with MiSeq, to TruSeq Sample Preparation and Custom Amplicon modules. You'll need a MyIllumina account to enroll. Register for a MyIllumina account or contact your local Account Manager for assistance.

Recent Publications

Bos KI, Schuenemann VJ, Golding GB, Burbano HA,

Waglechner N, et al. (2011) A draft genome of *Yersinia pestis* from victims of the Black Death. *Nature* 478: 506-510.

Wang D, Wang H, Zhou Y, Zhang Q, Zhang F, et al. (2011) Genome sequencing reveals unique mutations in characteristic metabolic pathways and the transfer of virulence genes between *V. mimicus* and *V. cholerae*. *PLoS ONE* 6: e21299.

Lu R, Neff NF, Quake SR, and Weissman IL (2011) Tracking single hematopoietic stem cells *in vivo* using high-throughput sequencing in conjunction with viral genetic barcoding. *Nat Biotechnol* 29: 928-933.

Castellarin M, Warren RL, Freeman JD, Dreolini L, Krzywinski M, et al. (2011) *Fusobacterium nucleatum* infection is prevalent in human colorectal carcinoma. *Genome Research*.

Baillie JK, Barnett MW, Upton KR, Gerhardt DJ, Richmond TA, et al. (2011) Somatic retrotransposition alters the genetic landscape of the human brain. *Nature*. [Epub ahead of print]

Wang K, Kan J, Yuen ST, Shi ST, Chu KM, et al. (2011) Exome sequencing identifies frequent mutation of ARID1A in molecular subtypes of gastric cancer. *Nat Genet*. [Epub ahead of print]

Myllykangas S, Buenrostro JD, Natsoulis G, Bell JM, and Ji HP. (2011) Efficient targeted resequencing of human germline and cancer genomes by oligonucleotide-selective sequencing. *Nat Biotechnol* 29: 1024-1027.

Maher B (2011) Human genetics: Genomes on prescription. *Nature* 478: 22-24.

Virgin HW and Todd JA (2011) Metagenomics and personalized medicine. *Cell* 147: 44-56.

Brown CT, Davis-Richardson AG, Giongo A, Gano KA, Crabb DB, et al. (2011) Gut microbiome metagenomics analysis suggests a functional model for the development of autoimmunity for type 1 diabetes. *PLoS ONE* 6: e25792.

Cooper GM and Shendure J (2011) Needles in stacks of needles: finding disease-causal variants in a wealth of genomic data. *Nat Rev Genet* 12: 628-640.

- International Symposium of the Association of Biomolecular Resource Facilities (ABRF)
March 17-20
Orlando, Florida

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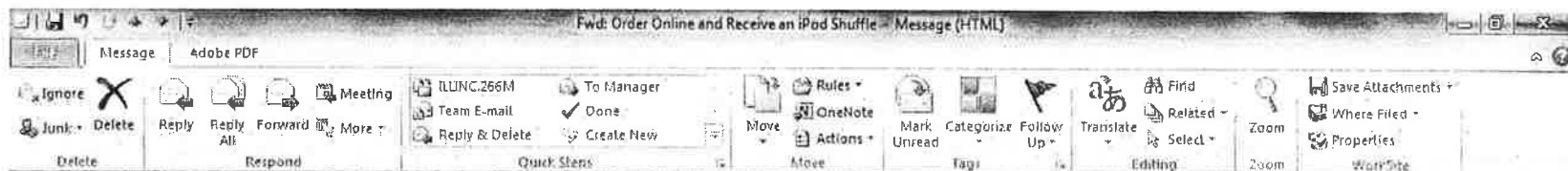
April 2014

Illumina Product Portfolio Expands to Support Cancer Research



Recent additions to the Illumina portfolio are designed to empower oncological research:

- The TruSeq® RNA Access Library Prep Kit reduces the sequencing depth required for FFPE and other degraded samples by isolating coding regions from human RNA.
- Using expert-defined content, the TruSight™ MySeq Sequencing Panel enables clinical research labs to interrogate 54 genes and exonic regions associated with myeloid malignancies in a single assay.



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Isothermal Quadruplex Priming Amplification Moves Closer to Point-of-Care MDx Applications

PCR Insider, 10/30/2014 - 15:19

assays based on LAMP and sold under the brand name **illumigene**. And earlier this year, Alere launched ...**Premier to Offer Members Access to Meridian's illumigene MDx Tests**

GenomeWeb Daily News, 09/03/2014 - 09:46

isothermal amplification, **illumigene**, commercial agreement, Clinical Genomics, PCR/Sample Prep) ...**Meridian Bio FY 2015 Guidance Below Street Expectations**

GenomeWeb Daily News, 09/02/2014 - 11:36

expectations for our foodborne category. A number of new product launches are anticipated, including **illumigene** ...**Meridian Bio FY Q3 Sales Inch Up**

GenomeWeb Daily News, 07/24/2014 - 14:53

that Meridian Bio added 30 new **illumigene** customers during the quarter and a total of 94 new assays were ...**Dx Focus: Meridian illumigene Assays; Biofactory FMR1 Identification Kit**

PCR Insider, 05/28/2014 - 15:10

by the US Food and Drug Administration, and are based on Meridian's **illumigene** platform, which uses ...**Canada Approves Meridian Bio's Molecular Assays for M. Pneumonia, B. Pertussis**

GenomeWeb Daily News, 05/28/2014 - 13:03

of the **illumigene** mycoplasma and pertussis products to the illumipro-10 test menu offers current illumipro-10 system ...**Meridian Bioscience Reports 6 Percent Jump in Fiscal Q2 Sales**

PCR Insider, 04/24/2014 - 09:37

illumigene Group A and Group B Streptococcus sales. **illumigene** C. difficile revenues also ...**Dx Focus: Quest's Focus Diagnostics; IMDx and Abbott; Meridian Bio;****DermTech International**

PCR Insider, 03/27/2014 - 15:59

to report a final result, increasing the time to manage the patient appropriately. With **illumigene** ...

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FDA Clears Meridian Illumigene Pertussis Test

GenomeWeb Daily News, 03/27/2014 - 15:44

appropriately. With **Illumigene** Pertussis, healthcare providers can collect, test, and treat same day for optimal ...

Meridian Reports 1 Percent Drop in Q1 Revenues; Mixed Results in Dx, Life Science Segments

GenomeWeb Daily News, 01/22/2014 - 10:23

Illumigene customers in Q1, a similar number as compared to the same period last year, and added 36 new tests ...

Meridian Sees Strong MDx Sales amid Lackluster Prelim Q1 Revenues; Opens Bioline Singapore Office

PCR Insider, 01/16/2014 - 15:04

for infectious disease in ambulatory patients, particularly its **Illumigene** Group B and Group A strep tests, along ...

Meridian's Fiscal Q1 Preliminary Results Fall Short of Expectations

GenomeWeb Daily News, 01/16/2014 - 09:43

that the company's **Illumigene** Pertussis test for diagnosing whooping cough "will provide meaningful revenues once FDA ...

Study Validates Lumora's Isothermal Amp-based C. Diff Assay Using Heat Elution Sample Prep

PCR Insider, 01/09/2014 - 14:57

the authors noted, the **Illumigene** assay, while fast and inexpensive, uses a seven-step, four-transfer process ...

Researchers Share Early Clinical Data on Performance of Quidel MDx Assays

PCR Insider, 11/21/2013 - 15:58

Strep groups and takes about 75 minutes to perform. The **Illumigene** test takes about the same amount ...

Meridian Bioscience Posts 13 Percent Uptick in Q4 Revenues; 9 Percent FY13 Growth

GenomeWeb Daily News, 11/07/2013 - 10:20

our focus on the **Illumigene** molecular system," Kraeutler said in a statement. He added that Meridian ...

Meridian Bioscience Initiates Guidance for FY 2014, Reaffirms FY 2013 Guidance

Guidance

GenomeWeb Daily News, 09/09/2013 - 13:30

on the **Illumigene** platform with tests for pertussis and chlamydia/gonorrhea expected to launch in the first half ...

Meridian Bio Q3 Revenues Increase 12 Percent

GenomeWeb Daily News, 07/25/2013 - 08:51

million, EPS is expected in the range of \$.86 and \$.91, (Meridian Bioscience, **illumigene**, quarterly ...

Dx Focus: Meridian Bioscience Illumigene Mycoplasma; CDC Novel Coronavirus Assay

PCR Insider, 06/13/2013 - 15:47

of in vitro diagnostics to detect the virus. (Meridian Bioscience, **illumigene**, US Centers for Disease ...

FDA Clears Meridian Bioscience M. Pneumonia MDx

GenomeWeb Daily News, 06/10/2013 - 13:38

that the company expects to file for FDA clearance for its **illumigene** pertussis test in the fall. (Meridian Bioscience, DNA amplification, **illumigene**, regulatory clearance, US Food and Drug Administration, Atypical ...

Meridian Bioscience Reports Flat Q2 Sales

GenomeWeb Daily News, 04/25/2013 - 09:35

of **illumigene** accounts to 1,026 servicing about 1,200 hospitals. Kraeutler added that the company anticipates clearance from the US Food and Drug Administration of the **illumigene** Mycoplasma assay "shortly," ...

Dx Focus: Meridian's Illumigene Group A, B Strep Tests; Cynvenio Biosystems' LiquidBiopsy Service

PCR Insider, 03/21/2013 - 15:35

with an estimated 15 million visits per year in the US. Clinical studies show that **Illumigene** Group A Streptococcus ...

Polls

Nature has called for increased sharing of code used as part of studies it publishes. Do you think this is a good idea?

☒ Yes. Access to code is important for replicating and building on previous work.

☐ Yes. This will reduce redundant efforts to develop such code.

☐ Maybe. It depends on how Nature enforces its pledge.

☐ No. Code used in research is often messy to be useful.

☐ No. It'll be too time consuming.

☐ I don't know.

Vote

View Results

FDA Recategorizes Meridian's Molecular Strep A and B Assays as 'Moderate Complexity' Tests

GenomeWeb Daily News, 03/19/2013 - 08:59

the benefits of Meridian's **illumigene** platform will be available to moderate complexity labs in US hospitals ...

On Heels of FDA Approval, Cepheid's Xpert CT/NG Test Performs Well in Multi-Center Clinical Study

PCR Insider, 03/14/2013 - 16:13

trials for two new isothermal **illumigene** assays for Chlamydia trachomatis and Neisseria gonorrhoeae ...

Meridian Bioscience NAAT for Group A Strep Shines in Multicenter Clinical Study

PCR Insider, 03/07/2013 - 16:20

assays, the authors said. Meridian's **illumigene** GAS test uses loop-mediated isothermal amplification, ...

Meridian Bioscience Reports 13 Percent Spike in Q1 Revenues Driven by Growth in illumigene Products

PCR Insider, 01/24/2013 - 16:26

that time the company's **illumigene** assays, which are based on loop-mediated isothermal amplification, have become a key growth driver at the company. In the first quarter, Meridian's **illumigene** portfolio ...

1 | 2 | 3 | next ›

Science	Business	Funding	GenomeWebinars
<p>Researchers from the Broad Institute, Massachusetts General Hospital, Yale School of Medicine, and elsewhere used a combination of genetic, gene expression, and epigenetic marker information to map the causal variants contributing to 21 inflammatory autoimmune conditions and begin unraveling their regulatory effects. Their results suggest that roughly 90 percent of the causal variants identified in these conditions so far fall in non-coding parts of the genome, affecting enhancers and other regulatory sites.</p>	<p>Qiagen has signed a master collaboration agreement to develop and commercialize companion diagnostics to pair with drugs being developed by Astellas Pharma for cancer and other diseases. The deal provides Tokyo-based Astellas access to Qiagen's development capabilities for assays based on PCR, next-generation sequencing, and multi-modal testing technologies using liquid and tissue biopsies. Qiagen noted that the agreement with Astellas is its eighth framework agreement for developing CDx tests in collaboration with biopharma companies.</p>	<p>The University of Oxford received a £35 million grant from the Higher Education Funding Council for England through its UK Research Partnership Investment Fund to launch the Precision Cancer Medicine Institute, a center that will use genomics and molecular diagnostics, among other technologies, to carry out research into cancer therapies. The center expects to receive more than £75 million from financial contributions and support in kind from partners in the project, such as Cancer Research UK, Roche Diagnostics, and GE Healthcare.</p>	<p>Novel Applications of NGS in Cancer Diagnostics</p> <p>Sponsor: Qiagen</p> <p>Date: Nov. 19</p> <p>This live online seminar will address new applications for next-generation sequencing in routine histopathological diagnostics and molecular pathology.</p> <p>Speakers: Reinhard Büttner, director of the Institute of Pathology at Cologne University Hospital; Vikram Devgan, head of Biological Research Content, Qiagen</p> <p>Register here.</p>

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GoldenGate® Indexing Assay Increases Sample Throughput

By combining sample indexing within the robust GoldenGate Assay, automation capabilities, and positive sample tracking with LIMS support, GoldenGate Indexing provides the highest level of throughput at the most affordable cost for low- to mid-plex custom genotyping screening.

Highlights

- **Highest Throughput:**
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well. Since the IllumiCodes are discreet within the well, each sample can be independently examined during downstream analysis.

Amplification and Signal Reading

Prepared samples are amplified using universal PCR primers labeled with Cy3 and Cy5 fluorescent dyes. The resulting fluorescently labeled PCR products are hybridized to a Universal BeadChip. The BeadChip contains randomly assembled universal beads, each displaying an IllumiCode corresponding to a specific loci. DNA will bind to the bead containing the complementary IllumiCode. Unbound DNA is removed and the remaining fluorescence signal levels read on the iScan system or BeadArray Reader for individual SNP genotype readout. This information is then analyzed for automated genotype clustering and calling. The entire assay can be completed in as few as three days.

Introduction

The GoldenGate Genotyping Assay is a highly successful genotyping technology proven in labs worldwide. In fact, it was used to make major contributions in the HapMap Project. Building on this strong foundation, the GoldenGate Indexing Assay allows researchers to pool multiple samples, increasing the number of samples that can be analyzed in a single run. With advanced automation and updates to Illumina LIMS (Laboratory Information Management System) to accommodate this new step, along with positive sample tracking, researchers now have the ability to screen up to 16 times as many samples per reaction as they could with the standard GoldenGate Assay. This dramatically increases throughput from 288 samples per day to greater than 2,000. Overall, researchers will realize a significant decrease in cost while maximizing throughput for low-complexity sample screening.

How GoldenGate Indexing works

GoldenGate Indexing, based on Illumina's BeadArray™ technology, maximizes the throughput of the original GoldenGate Assay (Figures 1 and 2). BeadArray technology uses IllumiCodes, unique 23-bp single-stranded DNA oligos, to correctly identify each DNA sample as well as the loci being interrogated. Because each IllumiCode is distinctive, multiplexing is possible. Current plexity ranges for GoldenGate Indexing include 96-plex, 192-plex, and 384-plex.

IllumiCodes Enable Pooling

During sample preparation, primers containing IllumiCodes and universal primer sites are hybridized to the DNA. Individual samples can be processed using oligonucleotide assay pools containing non-overlapping IllumiCodes. This enables pooling of multiple samples into a single

Illumina LIMS and Automation Control

The GoldenGate Indexing assay is highly automated, maximizing throughput. Robotic liquid handlers automatically process samples through each step of the assay, enabling the assay to run with minimal hands-on operation. Pre-amplification steps are performed via a larger 96-tip-based robot, and post-amplification steps via a standard 8-tip robot.

Figure 1: Universal-32 beadchip



GoldenGate Indexing Assay products are hybridized onto the Universal-32 BeadChip for individual SNP genotype readout.

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